Global Health
EDCTP3

Global Health EDCTP3 Work Programme 2026

Co-funded by
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Annex 1 to Governing Board decision No. GH-EDCTP3-GB/28/2025.

The Work Programme 2026 of Global Health EDCTP3 Joint Undertaking was adopted by the Governing Board on 2 December 2025.

In accordance with Council Regulation (EU) 2021/2085 and with Article 33 of the Financial Rules of the Global Health EDCTP3 Joint Undertaking.

The Work Programme is made publicly available after its adoption by the Governing Board.

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List of acronyms

Acronym/Abbreviation	Full title/Definition
AAP	Additional Activities Plan
Africa CDC	Africa Centres for Disease Control and Prevention
AMR	Antimicrobial Resistance
ARIPO	African Regional Intellectual Property Organisation
AU	African Union
AUDA-NEPAD	African Union Development Agency-New Partnership for Africa's Development
AVAREF	African Vaccine Regulatory Forum
BCG	Bacille Calmette-Guérin vaccine
BOA	Back-office arrangements
CA	Contractual Agent
CAAR	Consolidated Annual Activity Report
CBO	Community Based Organisations
CEPI	Coalition for Epidemic Preparedness Innovations
CHMP	Committee for Medicinal Products for Human Use
COVID-19	Coronavirus disease 2019
CSA	Coordination and Support Action
CSO	Civil Society Organisations
CTIS	Clinical Trials Information System
DALYs	Disability-adjusted life years
DDs	Diarrhoeal Diseases
DG	Directorate-General
DG BUDG	Directorate-General for Budget
DG RTD	Directorate-General for Research and Innovation

DHSC	UK Department of Health and Social Care
DNDi	Drugs for Neglected Diseases initiative
DPO	Data Protection Officer
EC	Ethics Committee
ECA	European Court of Auditors
ED	Executive Director
EDCTP	European & Developing Countries Clinical Trials Partnership
EDCTP AO	EDCTP Africa Office
EMA	European Medicines Agency
EU	European Union
FAIR	Findable, Accessible, Interoperable, Reusable
FR	Financial Regulation
FWC	Framework Contract
GB	Governing Board
GF	Gates Foundation
Global Health EDCTP3 JU	Global Health EDCTP 3 Joint Undertaking
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
HR	Human resources
IHI	Innovative Health Initiative Joint Undertaking
JU	Joint Undertaking
IAC	Internal Audit Capability
IAS	Internal Audit Service
ICAM	Internal Control and Audit Manager
ICF	Internal Control Framework
ICP	Internal Control Principles

IT	Information and communication technology
IKAA	In-kind contributions to additional activities
IKOP	In-kind contributions to operational activities
IPC	Infection Prevention and Control
LMICs	Low and Middle Income Countries
MAV+	Manufacturing and Access to Vaccines, medicines and health technologies
M&E	Monitoring & Evaluation
MMVC	Multi-Stage Malaria Vaccine Consortium
MoU	Memorandum of Understanding
MRC	UK Medical Research Council
Mtb	Mycobacterium tuberculosis
NCDs	Noncommunicable diseases
NIDs	Neglected Infectious Diseases
NPHIs	National Public Health Institutes
NTDs	Neglected Tropical Diseases
OAPI	African Intellectual Property Organisation
OJ	Official Journal of the European Union
PEP	Post-Exposure Prophylaxis
PPMT	Public procurement management tool
REA	Research Executive Agency
RIA	Research and Innovation Action
R&D	Research and Development
R&I	Research and Innovation
SARS-CoV2	Severe acute respiratory syndrome coronavirus 2
SC	Scientific Committee

SDGs	Sustainable Development Goals
SG	Stakeholders Group
SIAP	Strategic Internal Audit Plan
SLA	Service-level agreement
SRIA	Strategic Research and Innovation Agenda
SSA	Sub-Saharan Africa
STIs	Sexually Transmitted Infections
TA	Temporary Agent
TB	Tuberculosis
TFEU	Treaty on the Functioning of the European Union
TRL	Technology Readiness Level
TTG	Time to Grant
TTI	Time to Inform
TTP	Time to Pay
UN	United Nations
UNGA	United Nations General Assembly
WASH	Water, Sanitation and Hygiene
WHO	World Health Organization
WHO-AFRO	World Health Organization African Region Office
WP	Work Programme

1. Introduction

1.1 Mission statement of the Global Health EDCTP3 Joint Undertaking

The Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3) exists to accelerate the clinical development, evaluation, and implementation of new or improved health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases[1], including (re-)emerging diseases, particularly those affecting sub-Saharan Africa (SSA). In addition, Global Health EDCTP3 funds activities for research capacity building in Africa, supporting networking and researchers' careers and strengthening national health research systems. Furthermore, the partnership facilitates alignment of public and private funders around a common Strategic Research and Innovation Agenda (SRIA).

In the context of the Commission's priorities of contributing to the United Nations Sustainable Development Goals (SDGs), in particular Sustainable Development Goal 3, the Comprehensive Strategy with Africa[2], the Global Approach to Research & Innovation[3], the AU-EU Innovation Agenda[4], and the new EU Global Health Strategy[5], the EU is committed to ensuring healthy lives and promoting well-being for all, to building an even stronger partnership between the two continents and to supporting the development of research and innovation capacities within Africa.

Global Health EDCTP3 builds on the first and second European & Developing Countries Clinical Trials Partnership (EDCTP) programmes. This new joint undertaking (JU) is a partnership between the European Union (EU), represented by the European Commission, and the EDCTP Association, currently representing 15 European and 31 African countries. The partnership aims to reduce the individual, social, and economic burden of poverty-related and neglected infectious diseases and strengthen research capacities to prepare and respond to emerging and re-emerging infectious diseases in SSA and across the world.

1.2 Background and link with the Strategic Research and Innovation Agenda

Global Health EDCTP3, which is the EU–Africa global health partnership, represents the third EDCTP programme. Its SRIA[6] supports international collaborations accelerating the clinical evaluation and implementation of interventions against poverty-related infectious diseases, including the neglected ones affecting SSA. By building research capacity, it also enhances the ability of SSA countries to identify and respond to key infectious disease health challenges.

Infectious diseases remain a major cause of death, disability, and ill health in SSA[7]. Diseases such as human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), malaria, tuberculosis (TB), respiratory infections, diarrhoeal diseases, and a panoply of neglected infectious diseases (NIDs) have a devastating impact on individuals and communities and delay national economic development[8].

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1 WHO's list of neglected tropical diseases covers a diverse group of 20 diseases caused by different pathogens that have diverse manifestations, life cycles, and methods of transmission. The Global Health EDCTP3's remit will cover the following diseases from this list: Buruli ulcer, dengue and chikungunya, dracunculiasis (guinea-worm disease), echinococcosis, food-borne trematodiases, human African trypanosomiasis (sleeping sickness), leishmaniases, leprosy (Hansen disease), lymphatic filariasis, mycetoma, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiases, taeniasis/cysticercosis, trachoma, and yaws. The Global Health EDCTP3's remit will not cover chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming.

2 https://ec.europa.eu/commission/presscorner/detail/en/fs_20_374

3 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2465

4 https://research-and-innovation.ec.europa.eu/document/download/c9c4eb8e-df0f-41e7-a322-891786fef29b_en?filename=ec_rtd_au-eu-innovation-agenda-final-version.pdf

5 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153

6 The Global Health EDCTP3 Strategic Research and Innovation Agenda

7 Keddy, Karen H et al. The continuing challenge of infectious diseases. The Lancet Infectious Diseases, Volume 24, Issue 8, 800 - 801.

8 Ismahene Y. Infectious Diseases, Trade, and Economic Growth: a Panel Analysis of Developed and Developing Countries. J Knowl Econ. 2022;13(3):2547–83. doi: 10.1007/s13132-021-00811-z. Epub 2021 Jul 21.

SSA is also at risk of emerging and re-emerging infections, such as mpox, Ebola, Marburg virus disease, Lassa fever, Yellow fever and, most recently, SARS-CoV-2, which imperil global health security[9]. The alarming rise of antimicrobial resistance (AMR) is compromising available treatments and undermining multiple branches of medicine that rely on effective therapies for infection control. A high level of AMR burden for several bacterial pathogens and pathogen–drug combinations has been reported present in the WHO African region showing a higher AMR related mortality in lower resource settings[10]. Changing patterns of disease, driven by the climate crisis and environmental degradation, exacerbate these challenges.

Combatting infectious diseases is central to achieving SDG3, to ensure healthy lives and promote well-being for all at all ages. Furthermore, preventing and treating infections supports progress towards multiple other SDGs, by reducing the economic burden on countries, enhancing child development, promoting gender equity and the interests of populations with major unmet medical needs, and ensuring that healthier populations contribute to greater productivity and national prosperity.

Despite some progress, the Global Action Plan for Healthy Lives and Well-being for All, launched at the United Nations General Assembly (UNGA) in September 2019, noted that extra efforts would be required if health-related SDGs were to be met by 2030. It identified research and development (R&D) as a key accelerator of progress and emphasised the importance of global collaboration and alignment.

For infectious diseases predominantly affecting low- and middle-income countries (LMICs), limited commercial incentives exist to encourage the substantial investment required to develop and evaluate new vaccines, diagnostics, and treatments. Innovative models of collaboration to develop and evaluate new medicinal products are therefore required across public and private sectors, national governments, and regional and global agencies.

As a strategic partner, the EU seeks to enhance cooperation with Africa to promote actions targeted to finding solutions to challenges that are global in nature, yet often negatively impact Africa hardest, such as infectious diseases. The Comprehensive Strategy with Africa, the Global Approach to Research & Innovation and the AU-EU Innovation Agenda are the EU's most recent policy initiatives that prioritise research and innovation as a key dimension of sustainable development. Moreover, the new EU Global Health Strategy offers a framework for EU health policies leading up to 2030, setting policy priorities and guiding principles to shape global health, including by tackling infectious diseases, and recognises Global Health EDCTP3 as a key initiative for supporting the implementation of the strategy[11].

Initially set up in 2003, EDCTP has established itself as the focal point of clinical research cooperation for infectious diseases between the EU, European and SSA countries. The Global Health EDCTP3 work programmes for years 2022-2025 addressed several key aspects of the SRIA (as updated by GB Decision N° GH-EDTP3-GB/20/2025 of 1 September 2025)[12].

Global Health EDCTP3 continues to build on and extend the platforms created by the EDCTP Association under the first and second EDCTP programmes, which contribute to the above-mentioned policies. This work programme sets out the activities to be carried out in 2026, building on the activities supported so far and focuses on the following topics:

- Global Collaboration Action for the development of TB drugs for therapy and chemoprophylaxis in adults and children in sub-Saharan Africa
- Global Collaboration Action for Prevention and treatment of Lower Respiratory Tract Infections (LRTIs) in sub-Saharan Africa

[9] Moyo E, et al. Emerging infectious disease outbreaks in Sub-Saharan Africa: Learning from the past and present to be better prepared for future outbreaks. Front Public Health. 2023 May 9;11:1049986.
[10] Reference: Lancet Global Health, VOLUME 12, ISSUE 2 E201-E216, FEBRUARY 2024.
[11] EU Global Health Strategy: better health for all in a changing world
[12] Global Health EDCTP3 Strategic Research and Innovation Agenda

- Global collaboration action towards a better prevention, treatment and clinical management of HIV co-infections or co-morbidities in sub-Saharan Africa
- Global Collaboration Action on climate and health in sub-Saharan Africa
- Training networks for sustained capacity building related to ethics, regulatory and pharmacovigilance
- Enhancing integrated research and healthcare in sub-Saharan Africa through digital innovation and Artificial Intelligence.

It is also foreseen to directly reach out to the research and innovation community without launching a call for proposals in case of a public health emergency with earmarked budget for this activity. The placeholder budget may be increased through contributions from the EDCTP Association and/or contributing partners, and/or by transferring funding from other topics, depending on the type and magnitude of public health emergency, and need for launching actions.

In addition, a grant to an identified beneficiary (IBA) is also included in this work programme to expand the EDCTP Knowledge Hub already hosted on The Global Health Network (TGHN) and extend the successfully developed connecting and convening approaches across all existing and future regional Networks of Excellence, as part of implementation of the WHO Guidance for best practices for clinical trials[13] and Global action plan for clinical trial ecosystem strengthening[14].

All topics planned for this work programme support South-North networking. This is reflected in the obligation to have at least one partner from EU member states or countries associated to Horizon Europe that is a member of the EDCTP Association and at least one partner from SSA countries that are members of the EDCTP Association.

1.3 Strategy for the implementation of the programme

To maximise the impact of the partnership, Global Health EDCTP3 focuses on strategically critical areas of unmet public health needs. Mechanisms are established to identify emerging priorities and opportunities. Global Health EDCTP3 issues annual calls for proposals that reflect specific current research needs for target diseases and research capacity development. Prioritisation is indicated in the SRIA[15] and takes account of the following criteria:

- **State of the product development landscape:** For each disease area, the current state of clinical development of interventions for prevention (including vaccination), diagnosis, and treatment will be analysed.
- **Priority infections:** Priority setting will be informed by analyses of disease burdens, changing patterns of disease, contribution of a weakened immune system, extent of unmet medical needs, and the potential impact on a disease as a public health problem.
- **Disease burden and treatment/prevention priorities:** These analyses will identify key knowledge gaps and need for new evidence.
- **Emerging opportunities of translational bottlenecks:** Global Health EDCTP3 will focus on points in the translational and implementation pathway that delay the clinical development and uptake of novel interventions, supporting effectiveness studies, pharmacovigilance, and product-focused implementation research as required.
- **Strategic engagement:** Committed to early engagement with WHO and other strategically important international and African partners, Global Health EDCTP3 will ensure global alignment of

13 Guidance for best practices for clinical trials
14 Global action plan for clinical trial ecosystem strengthening
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its policies and priorities and promote coordinated responses to evidence gaps and capacity-building needs.

- **Strategic portfolio:** Global Health EDCTP3 will aim to develop and sustain a strategic portfolio across disease areas, types of intervention, and types of study. It will balance short-term and long-term priorities and funding across targeted diseases, with a view to supporting intervention research that is most likely to produce significant reductions in disease burden and overall mortality. In some areas, a portfolio approach will be used in prioritising and selecting different intervention candidates for funding.

Priority setting aims to balance the need for an overarching framework to guide the work of Global Health EDCTP3 with the flexibility to respond to emerging opportunities and health challenges. This annual programme includes details of the specific calls for proposals for the year 2026.

On the side of launching calls for proposals, the focus for the year 2026 is to expand on the investments made in previous years, including the 2022-2025 work programmes, based on the programme's criteria for prioritisation of funding. The strategy process for developing the 2025 work programme was launched with discussions and a meeting of the Scientific Committee and the same approach is taken for developing the 2026 work programme. With the Stakeholders Group fully operational, their input has been sought at topic level with no detailed information on the topics given, as members may be involved in applications to calls for proposals. Dedicated consultations on specific areas are held in different formats, as appropriate. Outreach to prospective contributing partners is a continuous effort pursued in a portfolio approach.

Building on the initial topics for training networks, under the 2023,2024 and 2025 work programmes respectively, strategic planning of the training networks for the coming years should take place during the year, with involvement of the EDCTP Association Africa Office.

1.4 Contributions from the EDCTP Association and contributing partners

The EDCTP Association continues to plan for significant contributions through in-kind contributions to additional activities (IKAA) in 2026. The IT tools for planning and reporting of AAs are now in place and have been utilised for the submission of the plans and reporting of incurred costs for years 2022-2024. It is worth noting that issues with the online tool have generated some challenges for data to be registered on time and for completeness during the reporting exercise 2024, in May/June 2025, but the JU is closely working in collaboration with the EC services to get support on this matter. The data consistency has always been cross-checked with the EDCTP Association to ensure qualitative input and accuracy. For the year 2026, the subsequent AA plan is expected to be submitted through the tool and in accordance with the AA plan 2026 annexed to this work programme (Annex 4.2). The guidance for the certification was prepared during 2024 and further finalised in collaboration with the EDCTP Association by the end of Q2 2025. An IKAA certification model is therefore expected to be used for the first time by the deadline of May 2026 and tested with the EDCTP Association and its member countries accordingly.

Close interaction with the EDCTP Association will be maintained in 2026 to ensure timely planning of future AAs, their reporting and certification of the IKAA.

In 2026, contributions from contributing partners are foreseen in certain topics as described in Annex 4.1. Furthermore, discussions with various other contributing partners are at different stages of maturity and are planned to be concluded in time for contributions for the work programme 2026.

1.5 Preparing grant agreements – reporting from ongoing grants

The grant agreement preparation of the two-stage calls of 2025 will start at the end of 2025 and will be concluded in 2026, while the grant agreement preparation of both the single-stage and two-stage calls of 2026 will start at the end of 2026 and will be concluded in 2027.

There will be reporting from ongoing grant agreements in 2026 and consequently assessment of the technical and financial reports. Global Health EDCTP3 expects to process 75 files with their related payments from actions financed mainly from the Work Programme 2022 (29 periodic reports) and from the Work Programme 2023 (37 periodic reports). Only nine periodic reports will stem from actions related to the Work Programme 2024.

In terms of type of periodic reports to be assessed, the vast majority (73 out of 75) will be interim reports, and only two final reports, meaning that Global Health EDCTP3 expects to close in 2026 two actions related to the Work Programme 2023.

2. Work Programme 2026

2.1 Message from the Executive Director and executive summary 2026

2.1.1 Message from the Executive Director

Dear colleagues, partners, and friends,

I am pleased to share with you the Global Health EDCTP3 Work Programme 2026, which leverages more than two decades of collaborative research and joint achievements under the first and second EDCTP programmes.

This fifth work programme is the outcome of a sustained and productive collaboration with the European Commission, the EDCTP Association, and our public and private strategic partners. It reflects our shared commitment to advancing innovative health solutions for infectious diseases – and their interaction with noncommunicable diseases – with particular attention to underserved populations in sub-Saharan Africa, while contributing to the strengthening of global health security.

In addition, this work programme reaffirms our dedication to the priority areas defined in the SRIA[16], and its alignment with the AU-EU Innovation Agenda and the EU Global Health Strategy. It demonstrates our resolve to remain responsive to the evolving global health landscape, while ensuring continuity in addressing the most pressing health challenges.

In 2026, Global Health EDCTP3 plans to launch three calls for proposals covering six research topics, for a total indicative budget of EUR 146,9 million. The topics will target specific disease areas as well as cross-cutting global challenges, including the critical interlinkages between climate and health.

Our calls for proposals will support a range of research and innovation actions (RIA) aimed at developing new or improved TB drugs, supporting the prevention and management of lower respiratory tract infections, and better prevention, treatment and management of HIV and its co-infections and co-morbidities.

The global challenge of climate and health will be addressed in a dedicated call aimed at improving health outcomes related to climate-sensitive infectious diseases and increased community and primary health care engagement.

Additionally, coordination and support actions (CSA) will support training and capacity-building activities in the areas of ethics, regulatory and pharmacovigilance, and enhance integrated research and healthcare through digital innovation and artificial intelligence.

As a means of increasing engagement of contributing partners and supporting large-scale activities, the approach of Global Collaborative Actions will be continued in this work programme. Therefore, the four RIA topics are open to leveraging funding from strategic partners. I am confident that by joining forces, our investments can achieve greater impact.

Building on the success of the Twelfth EDCTP Forum, held in Kigali, Rwanda, in June 2025, I am pleased to announce the forthcoming Thirteenth EDCTP Forum, which will take place in Madrid, Spain, in 2027. Preparations for this flagship event will commence in 2026, in close collaboration with the EDCTP Association and our hosts in Spain, the Institute of Health Carlos III Health (ISCIII), under the Ministry of Science, Innovation and Universities, and the CSAI Foundation (FCSAI), under the Ministry of Health.

To conclude, I wish to thank the Global Health EDCTP3 Scientific Committee and Stakeholders Group for their precious input into building this work programme, and the Programme Office in Brussels for steering its implementation.

I look forward to our continued collaboration in advancing the new activities, partnerships, and strategic initiatives that will emerge from this work programme.

Dr Michael Makanga

Global Health EDCTP3 Executive Director

[16] The Global Health EDCTP3 Strategic Research and Innovation Agenda

2.1.2 Executive summary 2026

This is the fifth work programme under Global Health EDCTP3. The topics are based on the SRIA adopted by the Governing Board[17]. Under the work programme 2026 three calls for proposals are expected to be launched:

1. A two-stage call covering 3 topics for Research and Innovation Actions (RIA);
2. A two-stage call covering 1 topic for Research and Innovation Actions (RIA);
3. A single-stage call covering 2 topics for Coordination and Support Actions (CSA).

With the following indicative budget:

Call	Budget (in million EUR)
Horizon-JU-GH-EDCTP3-2026-01-two-stage	88.9
Horizon-JU-GH-EDCTP3-2026-02-two-stage	25.0
Horizon-JU-GH-EDCTP3-2026-03-single-stage	33.0
Total	**146.9**

The work programme also foresees other actions, including: (a) expansion and consolidation of the EDCTP Knowledge Hub and (b) funding to be mobilised in case of a public health emergency.

The total operational budget 2026 covering those activities corresponds to **EUR 148.9 million** as detailed in section 3 of this document.

In the context of the work programme and calls 2026, following the pilot of work programme 2025, the JU will continue the use of grant agreements under three topics, taking the form of lump sum actions as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu).

2.2 Operational activities of Global Health EDCTP3 for 2026

2.2.1 Objectives, indicators and risks

Global Health EDCTP3 pursues two **overall objectives (OO)**, as defined in the Council Regulation 2021/2085[18] and the SRIA: (1) reduce the individual, social, and economic burden of infectious diseases in SSA through the development and uptake of new or improved health interventions, and (2) increase health security in SSA and globally, especially in the context of environmental change and the climate crisis, by reducing outbreak/ pandemic risks and strengthening antimicrobial resistance (AMR) response capacity.

[17] The Global Health EDCTP3 Strategic Research and Innovation Agenda
[18] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

These two overall objectives are operationalised through five specific objectives (SO) summarised below[19]:

- **SO1 - Advance biomedical interventions:** late-stage trials and product-focused implementation research.
- **SO2 - Build research capacity:** people, institutions, and systems.
- **SO3 - Enhance coordination:** North-South-South partnerships, alignment and leverage of resources.
- **SO4 - Strengthen epidemic preparedness**: networks, cohorts, data platforms, emergency response.
- **SO5 - Build partnerships and strategic alliances:** cross sector partnerships to maximise impact and cost-effectiveness.

The OO/SO framework cascades into **annual operational objectives** for WP2026, each linked to indicators already defined in (and fully aligned with) the JU M&E Framework (see section 2.2.4). Progress will be reviewed quarterly and synthesised annually to determine contribution to OO and SO.

The Operational objectives for WP2026 and their respective indicators are listed in table below.

Operational objectives for WP2026	Indicators
1. Launch grant calls, evaluate proposals & select grantees for clinical research, capacity building, networking & epidemic response	• # calls & call topics for grant proposals launched • # proposals submitted • average evaluation scores of proposals • success rate - % proposals retained • # projects selected for funding, with signed Grant Agreements
2. Fund RIA and CSA grants & monitor their implementation for progress, compliance, and quality standards	• grant amounts allocated to projects (EUR), committed and actual • % periodic reports (REPAs) submitted and approved within time limits • # and % projects fully implemented and closed
3. Provide guidance to JU grantees & other clinical research implementors on implementation of clinical research projects	• # legal, finance & project management trainings organised for beneficiaries of Global Health EDCTP3 funded projects • # unique participants in legal, finance & project management trainings organised for beneficiaries of Global Health EDCTP3 funded projects • # and % Global Health EDCTP3-funded projects whose team members attended legal, finance & project management trainings organised for Global Health EDCTP3 funded projects

[19] Full description of each of the 5 Objectives is available in SRIA (2025 version)

4. Raise awareness among relevant stakeholders about Global Health EDCTP3 objectives, results, priorities & grant opportunities	• # events where presentation about Global Health EDCTP3 was included in the agenda • # impressions and views of Global Health EDCTP3 posts through online media • # subscribers/followers to Global Health EDCTP3 social media outlets (incl. newsletter) • # public grant portals with which Global Health EDCTP3 shares data on funding of clinical research
5. Broaden engagement of countries & strategic actors in the JU initiatives	• # stakeholders with which Global Health EDCTP3 held discussions about potential collaboration / to maintain existing collaboration • # entities with which Global Health EDCTP3 has formal collaboration agreements • financial (€) and in-kind contributions, committed and actual, in addition to EU funds • # and % of newcomer organisations in JU-funded projects (by types and countries)
6. Ensure efficient & effective operational management of the JU to support programme implementation	• HR - occupancy rate • JU budget implementation and execution • payments made on time - # and % • proposals/grants for which TTI, TTG, TTP[20] were within established limits - # and % • # annual meetings of Global Health EDCTP3 governing & advisory bodies • # decisions/written procedures adopted by Global Health EDCTP3 Governing Board

Table 1: Operational objectives for the Work Programme 2026

In addition to monitoring the attainment of operational objectives and KPIs as part of the work programme 2026 implementation, the JU Programme Office will collect data for tracking the attainment of JU longer-term results and impact, by tracking output and outcome-level result indicators as defined in the M&E Framework (see section 2.2.4).

Risks

Risk management is a proactive process for identifying and assessing any event that could pose a threat to the achievement of the Global Health EDCTP3 objectives and determining how the

[20] TTI: time to inform - the number of days between the application deadline and the date candidates are informed of the selection outcomes; TTG: time to grant - the number of days between the application deadline and the date the grant agreement is signed; TTP: time to pay - timeframe for disbursing pre-financing, interim payments, or final payments after the relevant reports are submitted and approved.

corresponding risks should be managed. Therefore, risks management is an integral element of the strategic planning and monitoring cycle.

In order to control the risks identified, the Programme Office ensures their monitoring and continuous reviewing, considering the corresponding mitigating measures identified and taking further actions where necessary to ensure controls remain effective. Relevant Global Health EDCTP3 financial needs and the budget for 2026 have also been appropriately estimated. The staff is regularly informed on the objectives, activities and new planning.

2.2.2 Scientific priorities, challenges and expected impacts

Despite much progress, infections such as TB, respiratory infections, climate change-provoked diseases, co-infections and co-morbidities related to HIV and other poverty-related infectious diseases, continue to be responsible for a high burden of disease in SSA. Besides their impact on individuals, infectious diseases impose a high economic burden on countries, impeding national development. The COVID-19 pandemic has shown that new infectious threats may appear and that, with the increased connectivity of different regions in the world, can spread rapidly and significantly impact the world. In addition, there is an increasing risk of malaria and other vector-borne diseases emerging in the EU in the future due to changing environmental conditions and global trends. Developing health technologies for the identification, treatment and prevention of poverty-related infectious diseases is therefore crucial to control these diseases, as well as to fight them once they have spread, protecting the health of citizens in the countries expected to be disproportionally affected (such as SSA) and in the European Union.

Global Health EDCTP3 works towards achieving scientific priorities related to implementation of clinical research to develop health technologies to prevent, detect and treat infectious diseases, as well as enhancing research and innovation coordination, supporting the training of SSA researchers and building strategic partnerships.

These investments will result in specific outputs and results, such as an increased number of new or improved health technologies and better use in SSA, stronger research and innovation capacity in SSA, an increased cost-effectiveness of European public investment and strengthened sustainable global health networks.

The long-term impacts of Global Health EDCTP3 are expected to reduce the socio-economic burden of infectious diseases in SSA and increase health security in SSA and globally.

2.2.3 Calls for proposals 2026 and other actions not subject to call for proposals

Described in Annex 4.1 to the work programme 2026.

2.2.4 Monitoring, evaluation, and impact assessment

Monitoring and Evaluation (M&E) Framework

In 2025, Global Health EDCTP3 developed a comprehensive M&E Framework to systematically track JU results throughout the programme lifecycle and to provide evidence for timely adjustments and strategic decision-making. The Framework includes:

- **Programme logic:** Defines the causal chain of expected JU results, showing how resources and activities are expected to generate outputs, lead to immediate outcomes, and contribute to longer-term outcomes and impact.

- **Comprehensive list of indicators:** Tracks implementation and achievement of expected results across all levels. It combines EC-mandated indicators with JU-specific ones. The former includes Horizon Programme Key Impact Pathways indicators (KIPs), measured directly by the Horizon Programme with data shared with each JU; common indicators, shared across all JUs; and indicators deriving from reporting requirements under Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[21].
- **Core Indicators:** A set of 23 key indicators drawn from the full list, providing a high-level snapshot of the JU's performance. While the comprehensive list of indicators enables an in-depth analysis, the core list provides a concise overview of the overall performance.

Implementation

Following M&E Framework approval by the Governing Board in September 2025, the Framework began implementation in autumn 2025 and is planned to continue through 2026. Key elements in this process include:

1. **Regular measurement cycles:** Starting with September 2025 and repeated every three months, the JU will collect and analyse data on selected subsets of indicators from the M&E Framework. The choice of indicators for each round will be guided by their relevance for ongoing advocacy, communication, and reporting needs, their alignment with the expected timing of changes based on the programme logic, and the feasibility of data collection given data availability and timelines.
2. **Baselines and targets:** For relevant indicators, the JU will establish baseline values (initial reference points) and set realistic targets in alignment with JU objectives, available resources, and industry-recognised standards, providing clear reference points to track progress and assess performance over time.
3. **M&E data ecosystem:** To manage the growing volume of data, the JU will establish a robust M&E data ecosystem by combining existing Microsoft 365 tools with clear processes for data collection, quality assurance, analysis, and reporting. This integrated digital environment will ensure seamless data flows, data security, and compliance with EC rules on data protection, enabling the JU to focus on insights for data-driven decision-making rather than on manual data processing.

[21] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

2.3 Support to the operations of Global Health EDCTP3

2.3.1 Back-office arrangements (BOA)

According to Article 13 of Council Regulation 2021/2085 establishing the JUs under Horizon Europe[22], the JUs under Horizon Europe shall achieve synergies via the establishment of back-office arrangements operating in some identified areas. The Council Regulation also underlines that these synergies should be implemented where screening of resources has proved to be efficient and cost effective, while respecting the autonomy and the responsibility of each Authorising Officer.

The back-office arrangements "*shall be provided by one or more selected joint undertakings to all others. Interrelated arrangements shall be kept within the same joint undertaking to the extent appropriate for efficient and effective implementation of the tasks concerned in order to ensure a coherent organisational structure*".

Accounting

Global Health EDCTP3 implements its financial rules [GB decision 22/2022] which define, inter alia, powers and responsibility of Global Health EDCTP3's Accounting Officer. They also make an explicit reference to the possibility that this function could be attributed to the Accounting Officer of the European Commission, and such option was effectively utilised by the JU in the past.

However, in October 2021 the European Commission announced the intention to terminate their role of the Accounting Officer of the JU, except for the treasury function, which became effective as of 1 December 2022. The resulting situation was tackled by applying the back-office arrangements solution for the accounting function of the JUs. In fact, within this solution, EU-Rail is now performing the role of the Lead JU and is also, being one of the respective three JUs (with the Clean Aviation JU and the SESAR 3 JU), acting in the role of the accounting service provider.

An accounting correspondent in Global Health EDCTP3 is also nominated to interact closely with the accounting officer.

A procurement contract was concluded in 2023 to provide accounting services via an external contractor for the annual audit of the JU's statutory accounts, as well as consulting services related to accounting and financial management. Therefore, the services of these companies will be also used in 2026 and onwards to support the annual audit of the JU's accounts and for in-house work on the annual accounts and the financial management of the JU.

Facility management

During 2026, the BOA Facility Management will start functioning. The concept note is expected to be adopted by the Governing Boards of the Joint Undertakings having their seat at the White Atrium building in Brussels, and the relevant Service Level Agreement (SLA) will be signed. In the previous years, the activities related to the White Atrium building facility management were carried out by informal arrangements by a single JU (Clean Hydrogen JU until 2024 and Chips JU afterwards). To align with Article 13 of the Council Regulation 2021/2085, a BOA Facility Management has been proposed. This section will be updated with further details when the concept note is adopted and the SLA is signed.

[22] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

Human resources (HR)

Article 13 of the Council Regulation 2021/2085 establishing the JUs under Horizon Europe[23] identifies human resources (HR) support among the areas where common back-office arrangements can be set up. The HR domain is a sensitive area for all JUs, where confidentiality is a key building block of effective HR policies and for staff management, considering the strategic objectives to be achieved. It is therefore welcome that the legislator focuses on the support area of HR where synergies can be achieved without impacting HR policies that must remain under the remit of the JU and ultimately under the responsibility of each Executive Director as appointing authority.

For what concerns the HR domain, the JUs explore synergies in different areas, such as:

- **Recruitment**: establishment of common recruitment procedures, mapping of procedures, sharing of the recruitment IT tool, etc.
- **HR strategies:** common workforce planning, policy developments and efficiency improvement measures, etc.
- **Digitalisation**: harmonisation of IT tools, shared practices, possibly obtaining a single contract for all JUs, etc.

These synergies aim to achieve a better harmonisation among the JUs, exploiting best practices, achieving efficiency gains and economy of scale.

Since the back-office arrangement for HR is implemented and from 2023, Global Health EDCTP3 shared reserve lists with other JUs and benefited from getting access to a reserve list from other JUs. More strategic use of joint recruitments for common functions will be pursued in 2026.

Procurement

A BOA in the field of procurement has also been set up to run common procurement procedures between JUs. In this regard, a Service Level Agreement for Procurement Services (“BOA Procurement”) has been signed between Global Health EDCTP3 and other JUs, and a joint bi-annual procurement plan has been agreed upon. For more information on the BOA procurement activities please see below section 2.3.3).

Information and communication technologies (IT)

In continuation of the long-lasting coordination and collaboration practice on information and communication technology (ICT), and following the signature of the SLA of the BOA ICT in January 2025, the JUs have developed and approved a common IT annual work plan for 2026. This plan identifies 7 action lines covering 4 service areas for 2026:

- Service area 1: Governance:
  - Common governance, decision-making and budget monitoring: in this area, the implementation of the IT annual work plan and budget for 2026 will be monitored, and the common annual work plan for 2027 will be prepared in view of an adoption by the BOA ICT Steering Committee before the end of 2026,
  - Management of shared infrastructure, which includes in particular the delivery of Infrastructure-as-a-service (IaaS) under MS 365 technology,
  - Investigation of AI implementation for the JUs.
- Service area 2: Management of shared infrastructure

[23] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

- Service delivery and monitoring of the service contract,
- Preparation of a procurement procedure for the establishment of an FWC for ICT managed services, in coordination with the BOA Procurement.

- Service area 3: Workplace services provision
  - Workplace service delivery and monitoring of the service contract,
  - Continuous improvement of infrastructure in the White Atrium building (especially the meeting rooms).
- Service area 4: Security and compliance management, which includes the continuation of the implementation of the requirements of the Cybersecurity Regulation, and follow-up of other security requirements. This also includes the monitoring of the common business continuity plan and disaster recovery plan (BCP/DRP).

Ten Joint Undertakings are signatories of the BOA ICT, co-led by the Clean Hydrogen JU and the IHI JU. The common work plan identifies, for each action, a specific JU lead responsible for implementing the action.

In addition to common actions defined in the BOA ICT common IT annual work plan, JUs continue their collaboration with other Commission services and IBAs, and implement their own specific actions as described in section. 2.3.4 Information Technology.

2.3.2 Communication, dissemination and exploitation

In 2026, all communication activities will be implemented in alignment with the Global Health EDCTP3 communication and brand strategies and will focus on the promotion of the 2026 calls for proposals, the promotion of activities and results from grants signed under work programmes 2022-2025, the promotion of other activities carried out by Global Health EDCTP3, such as contributions to events and meetings or the activities of the members of the JU, and the organisation of the Thirteenth EDCTP Forum.

With the launch of the 2026 calls, coordinated communication activities will be undertaken to ensure that a broad range of relevant stakeholders learn about the new funding opportunities. Info Day sessions will be organised to provide details on the calls for proposals and social media activities will be launched. These events and activities will focus on both scientific content and administrative aspects, so that applicants have a good understanding of the specific requirements and conditions of the Global Health EDCTP3 calls. This is done to ensure that Global Health EDCTP3 attracts the broadest possible range of relevant applicants and involves partners at all levels to achieve its goals. In this context, to also reach Franco/Lusophone countries, it is planned to organise Info Day sessions in French and Portuguese, in collaboration with the French and Portuguese members of the EDCTP Association.

Particular attention will continue to be paid to ensuring good understanding amongst applicants and grantees about the legal obligation to ensure affordable access and how this is translated into contractual obligations for relevant grants and reports, as applicable, as well as the role of scientific project leaders, a novelty under Global Health EDCTP3 compared to EDCTP2. In order to reach out to regional stakeholders, and especially potential applicants in SSA countries, the EDCTP Association's Africa Office will support the activities undertaken by Global Health EDCTP3.

As strategic discussions and actions are carried out with contributing partners, for example, these will be supported by relevant communication activities. Additionally, a Global Health EDCTP3 online networking platform launched in 2025 is foreseen for the 2026 calls for proposals, building on the experience of the 2025 pilot. It will support future applicants in finding partners, forming consortia, and exploring co-funding opportunities with potential contributing partners.

The Thirteenth EDCTP Forum will take place in Spain in 2027. Over 1,000 participants are expected to attend the event, including representatives from research institutions and universities, the larger scientific community, health care providers, governments, regional bodies, regulators, civil society, and public and private research and development partners. During the course of 2026, Global Health EDCTP3 will actively promote the event and opportunities for participation, such as sponsorship and the submission of scientific abstracts, applications for scientific symposia, and prize nominations through its communication channels. A dedicated website will be created for the event.

As relevant and appropriate, Global Health EDCTP3 will contribute to exploiting and disseminating results from its predecessor programmes. This can occur by selecting follow-on grants that build on results from previous EDCTP programmes, where applicable, and/or by collaborating with the EDCTP Association to develop tailored communications materials and jointly organising events or presenting the results and impact of the EDCTP programmes at conferences and meetings. Synergies in exploitation and dissemination are particularly relevant in the outreach to countries in SSA and in Europe.

Throughout 2026, work will continue to further enhance and maintain the Global Health EDCTP3 website, especially when it comes to building a robust projects area and showcasing results and insights.

Moreover, the key activities and results of Global Health EDCTP3 will be promoted via the monthly newsletter and on social media, especially LinkedIn, where Global Health EDCTP3 has more than 20,000 followers.

2.3.3 Procurement and contracts

In order to reach its objectives and adequately support its operations and infrastructures, Global Health EDCTP3 will allocate funds to procure the necessary services and supplies. In order to make procurement and contract management as effective and cost-efficient as possible, Global Health EDCTP3 makes use of Service Level Agreements (SLAs) concluded with relevant Commission Services and inter-institutional framework contracts (FWCs) available to them.

In 2026, Global Health EDCTP3 foresees to implement existing Framework contracts (FWCs). When the services needed are not covered by FWCs already in force, Global Health EDCTP3 will launch procurement procedures for middle or (very) low-value contracts.

The Governing Board adopted its decision GB/10/2023 on 3 August 2023 approving the principle of back-office arrangements between joint undertakings on procurement. Prior to that, the interim Executive Director had signed an SLA with several other JUs setting out the frame and conditions for this arrangement, as mentioned in the section 2.3.1 above. Clean Aviation JU acts as the lead JU in this context, coordinating the back-office arrangement and providing services to other JUs. Its Executive Director is responsible for the organisation, oversight and coordination including reporting. It is supported for this purpose by the Europe's Rail and EuroHPC JUs. This arrangement enables the JUs to carry out common procurement procedures. Such synergies imply that Global Health EDCTP3 may save substantial human resources as its staff in charge of procurement may often rely on a common procedure led by the Clean Aviation JU instead of launching its own. In addition, financial savings are also expected given that the contracts to be awarded relate to larger needs, which are pooled between JUs. This arrangement has already proved efficient, and it is expected that it will keep being used for a large share of the procurement needs of Global Health EDCTP3 in the future.

The Service Level Agreement for Procurement Services ("BOA Procurement") also includes a joint bi-annual procurement plan.

The Back Office Arrangements in Procurement ('BOA Procurement') will continue to create synergies among its members across 2026-2027 as reflected in the endorsed by the Steering Committee Joint Public Procurement Planning ('JPPP').

Among the inter-institutional tender procedures planned for the 2026–2027 period, the renewal of a framework service contract for managed IT services is the most strategic priority.

It has been proven that by pooling a negotiation power, the BOA joint administrative calls for tenders draw the attention of higher number of economic operators, ensuring competitive bids and robust market responses.

Finally, in 2026 the BOA will further prioritise the digitalization of contract management processes with a strong focus on streamlining its operating framework.

The below Global Health EDCTP3 procurement indicative planning and budget is therefore also impacted by the joint JU procurement planning 2026 and their successive updates.

For the procedures still organised by Global Health EDCTP3, the IT and procurement management tool PPMT that has been developed by the Joint Research Centre will be the main tool to be used in 2026.

Title	Indicative budget (EUR)	Type of procedure	Indicative schedule
IT support and supplies (implementation of BOA procurement and specific Global Health EDCTP3 infrastructure)	400,000	Specific Contracts/order forms implementing a FWC or Negotiated procedure for middle or low value contract	Yearly
Office Furniture	20,000	Specific Contracts/order forms implementing a FWC	Yearly
Water supplies & fountains	2,000	Negotiated procedure for low-value contract	Q1 to Q4 2026
Communication and event services and supplies	450,000	Specific contracts/order forms implementing a FWC or negotiated procedure for middle or low-value contracts	Q1 to Q4 2026
Catering services	20,000	Specific Contracts/order forms implementing a FWC or negotiated procedure for low-value contracts	Yearly
Team Building and Training	60,000	Specific Contracts/order forms implementing a FWC or negotiated procedure for low-value contract	Yearly
Assistance and support of external experts and other services contracts	320,000	Ad-hoc expert contracts based on a Call for expression of interest (CEI) or	Q1 to Q4 2026

		implementation of a FWC	
Implementation of the Back Office Arrangements (BOA) for Accounting services	120,000	Implementation of Framework contracts External Support to the Back Office Arrangement for the Joint Undertakings for Statutory Audit Services (Lot 1) and Accounting Services and Other Assurance Engagements (Lot 2) for 10 JUs and for 5 years duration	Yearly
New tool for budget preparation and financial reporting	60,000	Specific contracts/order forms implementing a FWC or negotiated procedure for low-value contracts.	Q2 to Q3 2026
M&E data project	100,000	Specific contracts/order forms implementing a FWC or negotiated procedure for middle or low-value contracts.	Yearly
Evaluation & Feedback services project	50,000	Specific Contracts/order forms implementing an FWC.	Yearly
Legal and operational support to data protection activities, including externalisation of DPO function (implementation of BOA procurement)	50,000	Specific Contracts/order forms implementing a FWC	Yearly
Data protection on-line register (implementation of BOA procurement)	10,000	Specific Contracts/order forms implementing a FWC	Yearly
Legal Assistance services (representation in litigation, legal support services for HR or IPRs etc.) (implementation of BOA procurement)	10,000	Low-value contract, ad-hoc expert contracts based on a Call for expression of interest or Specific Contracts/order forms implementing a FWC	Q1 to Q4 2026

Table 2: Indicative procurement procedures in 2026

This list must not be considered exhaustive and other procurement procedures may need to be launched within the budgetary limits approved by the Global Health EDCTP3 Governing Board and the budget flexibility clause. The Executive Director shall report to the Governing Board about the procedures put in place as part of the CAAR 2026.

2.3.4 Information Technology

With regards to Information Technology, the main objectives of Global Health EDCTP3 in 2026 are to:

- Further fine-tune the Global Health EDCTP3 IT infrastructure.
- Strengthen further the collaboration with the other JUs through the back-office arrangements on IT.
- Define the data architecture and support the Monitoring and Evaluation framework from a technical IT perspective.

In 2025, Global Health has taken the necessary steps to implement the EU cybersecurity regulation, and this will continue during the year 2026.

During the year 2025, Global Health EDCTP3 used its new website https://www.global-health-edctp3.europa.eu/ and email addresses @global-health-edctp3.europa.eu and obtained from DG DIGIT new EU Login(s) for the staff. The confirmation of successful IT migration, final tests and back-up plan was implemented by the end of Q1 2025, when all EC IT equipment was released back to DG DIGIT services. The migration being completed, the JU is expected to be completely IT-autonomous for 2026 and the following years. By mid-2025, the JU is actively involved to ensure full migration based on ongoing planning or addressing the final problematic issue for some tools:

- MIPS: mission payment (auto completion of payment is still not working)
- PPMT: migration in production is ongoing
- SUMMA: the JU is migrating to a new accounting system by 1 January 2026 (see below).

In alignment with the practices of the other JUs and under the supervision of the BOA IT, Global Health EDCTP3 is part of the implementation of the next-generation secured network with the European Commission (also known as S-Testa) and from a connectivity perspective the JU will continue to on-board telecommunication services and integrate them with Microsoft 365 in 2026.

In the broader context of the back-office arrangements on IT, Global Health EDCTP3 will continue in 2026 to collaborate with the other JUs in the fields of shared IT infrastructure, inter-JU IT governance, IT framework contracts, tools and services and Security and compliance management.

To ensure a safe and FAIR (findable, accessible, interoperable, reusable) collection of data and results of JU-funded projects as well as other JU initiatives, the JU will collaborate with IT external consultants to establish and implement in 2026 a robust M&E data ecosystem as described in section 2.2.4 above.

Additionally, various possibilities for tracking of publications funded by Global Health EDCTP3 and related analyses will be further investigated.

In order to foster collaboration and information sharing among staff, as well as easy access to data, reporting and systems, a private, secure Intranet was created and will be further developed in 2026.

The replacement of the corporate accounting system ABAC with SUMMA is expected to occur in 2026 and the JU has prepared the necessary steps to ensure a smooth transition to SUMMA. The SUMMA Business Partner module (replacing the ABAC LEF/BAF monitoring for the vendor and customer accounts) is already implemented. IT and financial colleagues have been trained accordingly in 2024 and 2025 for smooth implementation from 2026 and onwards.

In 2025, the JU moved to its new premises located at the second floor of the White Atrium building. The JU set up new offices for all its staff, new meeting rooms for internal use and external stakeholders, including a new Board room. With most of the meetings with external participants being conducted via teleconference, the JU office new meeting rooms were therefore equipped with minimal video-conference equipment and will be further equipped in 2026. Further works relevant to ventilation took

place during 2025, concluding the final renovation works scheduled. For 2026 and the following years, the new premises are fully functional for the Global Health EDCTP3 staff.

Global Health EDCTP3 will continue working to align with the corporate requirements in terms of cybersecurity and data protection. In addition to the BOA IT common JU's IT strategy, Global Health EDCTP3 is planning to further develop its own policies and strategy for aspects specific to its Information Systems Internal management in 2026.

Further, in 2026, the JU will continue to implement effective document management, covering both electronic and physical records. The document management implementation will contribute to meet our transparency and accountability obligations as well as ensure evidence of the Global Health EDCTP3 activities and retention of its legacy.

2.3.5 Data protection and access to documents

Regarding data protection, Global Health EDCTP3 will continue to ensure compliance with Regulation No 2018/1725 laying down data protection obligations for the EU institutions and bodies when processing personal data. Global Health EDCTP3 is liaising with the relevant services of the European Data Protection Supervisor and contributing to the activities of the inter-institutional data protection networks to raise awareness among the staff and stakeholders.

The role of the Data Protection Officer (DPO) is exercised by a Legal Officer of Global Health EDCTP3, assisted by an external contractor. Global Health EDCTP3, as a controller, maintains a record of processing activities under its responsibility in a register and makes this register publicly accessible. In addition, Global Health EDCTP3 takes appropriate measures to provide transparent information, communication and modalities for the exercise of the rights of the data subject. A collection of privacy notices is available in the JU's website. More information is available on the Global Health EDCTP3data protection and legal notices pages[24]. In accordance with the Council Regulation and the back-office arrangements, Global Health EDCTP3 will continue in 2026 to develop synergies and efficiencies in data protection related activities with other Joint Undertakings, as in 2025, regarding the further development of the on-line central register (FWC led by Europe's Rail JU in which Global Health EDCTP3 participates) and the support by external contractors on data protection services (FWC led by SESAR JU in which Global Health EDCT3 participates).

Regarding access to documents, Global Health EDCTP3 will address any requests for access to documents according to Regulation No 1049/2001, in a spirit of openness and transparency, in order to bring its activities and outputs closer to the public by giving the opportunity to the public to monitor its work.

2.3.6 Other support operations

As already mentioned above, Global Health EDCTP3 will use existing arrangements amongst the JUs established under Horizon Europe, such as in the areas of IT, HR and procurement. Additional areas for collaboration through back-office arrangements will be explored.

Global Health EDCTP3 will continue to use the Horizon Europe corporate IT tools for encoding work programme call topics for publication to submission of proposals through evaluation, grant preparation and grant management and follow-up (eGrants suite of online tools). The reimbursement of evaluation experts will continue to be handled by the Research Executive Agency (REA) as part of the use of the Horizon Europe IT tools, based on an SLA signed between Global Health EDCTP3 and REA.

[24] https://globalhealth-edctp3.eu/legal-notice-and-privacy

In addition to collaborating through back-office arrangements as explained above, the JUs also work together informally at all levels of the organisations: Executive Directors, Heads of Unit of Administration and Finance, IT Officers, HR Officers, Scientific Project Officers, etc.

As several other JUs, Global Health EDCTP3 will continue to participate into the EU Agencies Network (EUAN) which provides support and information sharing on relevant matters, such as HR.

In 2025, Global Health EDCTP3 moved to its new premises located on the second floor of the White Atrium building, on the basis of a new rental contract directly signed with the owner of the building, starting from 1 October 2024. Works took place that set up the new offices between October and December 2024, as well as ventilation works during July and August 2025. These new offices fully accommodate the needs of the Programme Office in terms of staff number and meeting facilities. For 2026 and the following years, the new premises are fully functional for the Global Health EDCTP3 staff.

2.3.7 Human Resources (HR)

2.3.7.1 HR Management

The objective of the Human Resources (HR) function within Global Health EDCTP3 is to support the organisation's strategic mission by attracting, developing, and retaining a highly skilled and motivated workforce, while fostering a positive, inclusive, and performance-driven workplace culture.

Key achievements in 2025

In 2025, Global Health EDCTP3 made significant progress in strengthening its human capital in line with its strategic vision. The year was marked by notable progress in recruitment, workforce development, policy enhancement, and organisational culture.

The HR function successfully facilitated the onboarding of 13 statutory staff members. Four interim staff and three corporate trainees were engaged across various functions. Their contributions helped streamline administrative and operational processes during a period of increased activity and growth.

Continuous learning remained a core element of the HR strategy. By the end of 2025, the JU recruitment in accordance with its establishment plan is expected to be finalised.

In 2025, external training opportunities were made available to all staff. To strengthen collaboration and enhance team dynamics, HR team offered a series of in-house coaching sessions aimed at supporting effective staff communication and collective performance.

The HR department successfully implemented the first round of contract renewals in full compliance with established policies and to further motivate and engage staff, a significant number of promotions were awarded throughout the year.

In 2025, the JU has also implemented an action plan to follow up on the staff survey initiated in 2024 and also in 2025. Following the staff survey results, a comprehensive HR action plan was developed and implemented, setting out clear objectives for career development and staff well-being. Some of the biggest achievements have been:

- New offices with the opportunity for the staff to collaborate in a nice working environment
- Learning and Development policies and follow-up of learning/training map
- Reclassification exercise
- Team buildings for the JU, and for the units/teams
- Training and coaching

- Other actions (fruits/plants/water/breakfast for newcomers and lunches for the JU staff, etc.)

Finally, to further foster a positive work environment, in-house mediation services have been introduced to address and prevent conflicts through constructive dialogue. This initiative represents a key HR measure that Global Health EDCTP3 has advocated extending to other JUs, as part of the BOA HR and in alignment with practices already implemented by JUs offering similar services.

Key objectives 2026

Staff engagement and feedback

As part of a continuous improvement approach, the JU will continue to launch staff survey was launched to assess employee satisfaction, workplace well-being, and organisational effectiveness, and also in the context as required by the JU Internal Control Framework. The feedback collected will guide future HR initiatives in 2026 and support the design of targeted well-being and engagement strategies, helping to foster a supportive, inclusive, and high-performing work environment.

Strategic objectives

The HR department of the JU will continue following up the staff survey results and action plan serving as a roadmap for 2026 and the coming years to ensure the HR function remains aligned with the operational needs and strategic vision of Global Health EDCTP3, and with EC guidelines and/or with the BOA HR recommendations.

Recruitment of staff

Global Health EDCTP3 will work in 2026 with a completed staffing plan, as all recruitment procedures for statutory staff have been finalised in 2025. In 2025, Global Health EDCTP3 welcomed its inaugural trainee in the Legal team, with additional trainees to be recruited through a joint call for corporate trainees in partnership with another Joint Undertaking. These initiatives reinforce Global Health EDCTP3's commitment to fostering young professionals, which will continue in 2026.

Overall, in 2026, Global Health EDCTP3 will continue to invest in staff, policies, and culture to ensure that the JU remains an employer of choice and a catalyst for innovation and impact in global health.

2.3.7.2 Strategy for achieving efficiency gains, synergies through back-office arrangements

Strategy for achieving efficiency gains, synergies through back office arrangements

According to Council Regulation (EU) 2021/2085, JUs shall achieve synergies via the establishment of back-office arrangements (BOA), operating in some identified areas. Article 13 identifies Human Resources Support among the areas where common BOA could be set up. In that context, CBE JU is the lead JU for the BOA HR with IHI JU as "back-up JU".

The BOA HR implements actions in three main areas of HR Support: recruitment, HR legal framework and HR digitalisation. Its objective is to maximise synergies among the JU's, harmonise procedures by valorising best practices, ensure coherent HR support services, achieve efficiencies and economies of scale, increase the negotiation power of JU's operating under the SBA towards contractors and service providers.

The JUs established under Council Regulation (EU) 2021/2085 will contribute to BOA HR Support, together with EuroHPC and SESAR JU[25] that will participate on specific initiatives in line with their internal priorities and according to their own specificities.

Scope of the BOA HR support

[25] SESAR JU despite being part of the SBA, is exempted by the provisions related to the Back-office arrangements.

In line with the proposal of an enhanced coordination of the Network of JUs' HR officers, the conclusion of a Service Level Agreement (SLA) among the JU's has been deemed necessary since a clear commitment to the execution of the BOA HR Annual Work Plans must be made by the JUs under the coordination of the Lead JU. Established in 2024, the BOA HR will build on the achievements of its first two years and will continue in 2026 to focus on the following key areas of HR support, while further developing new projects and activities:

Recruitment

- **Alignment and harmonisation of the JUs' recruitment processes**: following its finalisation in 2025, the common selection process guidelines—designed in accordance with best practices and the applicable legal framework—will be implemented across all JUs, ensuring a consistent and transparent approach whenever a selection procedure is launched.
- **Organisation of joint selection procedures to increase efficiency gains**: the JUs will strive to organise joint selection procedures for common profiles with same grades. This practice already in place, will be strengthened in 2026.
- **Establishment and sharing of reserve lists:** where appropriate, the JUs will continue to share their reserve lists to shorten their recruitment processes and time-to-recruit.
- **Inter-JU Competency framework:** the BOA HR will continue to work on the common inter-JU competency framework and harmonization of job profiles, reinforcing consistency and clarity across all roles and supporting more effective HR management in the JUs.

HR legal framework

The JUs share a common legal framework in the HR domain, therefore, additional synergies can be achieved by enhancing the existing collaboration in this area. The focus in 2026 will be on:

- **Staff Well-being and Conflict Prevention:** expanded in 2025 with 4 additional members further to a new call for expression of interest, the JUs will continue to offer to the JUs staff a common network of Confidential Counsellors. Information campaigns and joint actions will be launched to promote staff well-being, raise awareness about psychological and sexual harassment, and implement preventive measures aimed at mitigating workplace conflicts. In this context the JU's will also increase the visibility of mediation services to JU's staff.
- **Collaboration with the EU agencies network (EUAN) and the EC**: the JUs will continue to attend EUAN meetings, including possible ad-hoc participation of the HR Officers to different working groups.
- The JUs will also continue strengthening their collaboration with DGHR /PMO about common HR matters. Notably, building on the recent reinforcement of the collaboration with DG HR, the latter and DG HR will explore the feasibility of working on new synergies including the possibility for JUs to join the Standing Working Party, JUs access to the newly developed modules of the HRT platform of DG HR and a more agile sharing of reserve lists among EU bodies.
- **BOA HR network**: the JUs HR Officers will continue their strong collaboration. A new multi-annual work plan which will include inter-JU new projects and activities will be developed and adopted by the BOA HR Steering Committee**.**

After two years of existence, the BOA HR will take stock of its experience and will reflect on the modalities of its governance.

HR digitalisation

In 2026, the JUs will continue to move towards a digitalisation of HR processes. The BOA HR will continue to share good practices in the use of HR IT systems.

2.3.7.3 Staff establishment plan

Table 3: Staff establishment plan 2026

Function group and grade	2025				2026	
	Authorised budget 2025		Actually filled at 31/12/2025		Authorised budget*	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD14	0	1	0	1	0	1
AD12	0	2	0	2	0	2
AD11	0	1	0	1	0	1
AD8	0	7	0	7	0	7
AD7	0	4	0	4	0	4
AD6	0	7	0	7	0	7
AD5	0	1	0	1	0	1
Total AD	**0**	**23**	**0**	**23**	**0**	**23**
AST5	0	1	0	1	0	1
AST4	0	1	0	1	0	1
AST3	0	0	0	0	0	0
Total AST	**0**	**2**	**0**	**2**	**0**	**2**
Total AD+AST	0	25	0	25	0	25
Total staff (incl. CA)	0	**36**	0	**25**	0	**36**

Contract Agents [26]	FTE corresponding to the authorised budget 2025	Headcount at 31/12/2025	FTE corresponding to the authorised budget 2026*
FGIV	7	6	7
FGIII	4	3	4
Total	**11**	**9**	**11**

**Adjustments to the staffing level may be decided by the Corporate Management Board of the European Commission after considering the budgetary top-ups by third country credits and other aspects.*

[26] Three (3) contract staff financed are financed from third countries contribution.

2.4 Governance activities

Following the successful establishment of Global Health EDCTP3, its governance, advisory and consultation bodies have also been set up and are fully operational.

According to the relevant provisions of the Council Regulation establishing the JUs under Horizon Europe, the bodies of Global Health EDCTP3 are:

- Governing Board
- Executive Director
- Scientific Committee
- Stakeholders Group
- In addition, an ad-hoc advisory group was created in 2025: The Advisory Group on Climate and Health Strategy (AGCHS).

2.4.1 Governing Board

The Governing Board is the decision-making body of Global Health EDCTP3. It has the overall responsibility for the strategic orientation, coherence with the relevant European Union objectives and policies and operations of the JU and supervises the implementation of its activities.

The Governing Board of Global Health EDCTP3 is composed of six representatives of the European Commission on behalf of the European Union and six representatives of the EDCTP Association on behalf of the African and European countries participating in the programme. It shall hold ordinary meetings at least twice a year, whereas extraordinary meetings may be convened at the request of the Chairperson, the Executive Director, the European Commission or the EDCTP Association. The meetings of the Governing Board are convened by the Chairperson. The agenda of the meetings and the decisions taken are made publicly available on the website of Global Health EDCTP3.

In 2026, it is foreseen that the Governing Board will hold 3 meetings, focusing on the strategic priorities and implementation of the activities of Global Health EDCTP3.

Further important decisions may be adopted via written procedures, which are launched by the Executive Director on behalf of the Chairperson of the Governing Board.

2.4.2 Executive Director

The Executive Director is the chief executive responsible for the day-to-day management of the JU. The Executive Director is the legal representative of Global Health EDCTP3 and is accountable to the Governing Board. He is supported in his activities by the Programme Office staff of the JU.

The initial mandate of the current Executive Director, Dr Michael Makanga, started in 2023 for a period of four years until 15 November 2027.

2.4.3 Scientific Committee

The Scientific Committee is the scientific advisory body of Global Health EDCTP3.

During 2026, the Scientific Committee will continue its important work of providing input on the scientific priorities to be addressed and the scope of the calls for proposals. The Scientific Committee is also consulted on the In-Kind contributions to Additional Activities (IKAA) plans.

In line with the Council Regulation establishing the JUs under Horizon Europe, the Chairperson shall prepare a report after each meeting of the Scientific Committee and submit it to the Governing Board.

For 2026, three meetings of the Scientific Committee are planned.

2.4.4 Stakeholders' Group

The Stakeholders' Group of Global Health EDCTP3 will actively provide input on the scientific, strategic and the technological priorities to be addressed by the JU as laid down in the SRIA[27] taking into account the progress and needs of the Global Health and adjacent sectors.

As foreseen in the Council Regulation 2021/2085 establishing the JUs under Horizon Europe[28], the Executive Director may advise the Governing Board to consult the Stakeholders Group on specific issues. Where such consultation takes place, a report shall be submitted to the Governing Board after the relevant discussion within the Stakeholders' Group and will be published on the website of the JU.

During 2026, three meetings for the Stakeholders' Group are planned.

When the occasion arises, a joint meeting of the Scientific Committee and the Stakeholders' Group may be held.

2.4.5 Advisory Group on Climate and Health Strategy (AGCHS)

With the overall objectives of reducing the individual, social and economic burden of infectious disease and increasing health security in SSA, Global Health EDCTP3 has a focus on overarching global challenges, including contributing to minimising the health impacts of climate-change-driven infectious diseases. Specific expertise in addition to the one expert already included in the Scientific Committee is needed to tackle these challenges. The legal basis of the establishment of the advisory group is the Global Health EDCTP3 GB Decision 13/2025, in application of Article 17(2)(x) of the Council Regulation 2021/2085.

To this end, in 2025, the Governing Board has appointed an Advisory Group on Climate and Health Strategy (AGCHS). The AGCHS has been appointed until 31 December 2025 and its mandate may be extended for an additional period of up to one year (up to 31 December 2026) by Decision of the Executive Director.

The AGCHS shall provide recommendations to the Executive Director in the form of reports in order to: (a) identify important and realistic short and medium-term priorities that will inform the formulation of a call for proposals and (b) identify the medium- and long-term research needs in SSA, which may be integrated into the remit of a successor to the Global Health EDCTP3 programme. The Executive Director may request from the AGCHS to provide recommendations on any other subject in the field of climate and health or other types of deliverables if appropriate. The AGCHS shall work under the supervision and instructions of the Executive Director and hold meetings upon his/her request.

[27] The Global Health EDCTP3 Strategic Research and Innovation Agenda
[28] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

2.5 Strategy and plans for the organisational management and internal control systems

The Global Health EDCTP3 Internal Control Framework (ICF) was adopted by the Governing Board in August 2023 (Decision GH-EDCTP3-GB/11/2023). The Global Health EDCTP3 Internal Control Framework is based on the framework adopted by the European Commission, which consists of five internal control components and 17 principles based on the COSO 2013 Internal Control-Integrated Framework.

The priority objective for 2026 remains to implement and maintain an effective internal control system so that reasonable assurance can be given that resources assigned to the activities are used according to the principle of sound financial management and control procedures in place give the necessary guarantees concerning the legality and regularity of transactions.

In Q1 2026, Global Health EDCTP3 will perform its annual ICF self-assessment exercise. The results of the ICF self-assessment will be presented in the Global Health EDCTP3 2025 Consolidated Annual Activity Report (CAAR).

2.5.1 Financial procedures

The Global Health EDCTP3 Financial Rules were adopted by the Governing Board by decision GH-EDCTP3-GB/22/2022. The workflows in place follow the financial rules, as adopted via the GB Decision abovementioned. The financial circuits are established to standardise the mandatory steps of the processing of financial transactions and to clarify who are the different actors and their responsibilities (administrative and operational expenditure). The financial circuits were adopted by the interim Executive Director by decision GH-EDCTP3-ED/21/2023. After the financial autonomy, the financial circuits have been revised; its third amendment was adopted on 4 December 2024 by decision GH-EDCTP3-ED/24/2024.

Financial procedures in the JU are also based on the controls embedded in Commission tools. In Horizon Europe, reporting and validation of costs (including evaluation experts) is implemented using the European Commission IT tools (SyGMa, COMPASS, ECS). In accounting, the controls are implemented using the accounting system ABAC.

2.5.2 Ex-ante and ex-post controls

The purpose of ex-ante controls is to ascertain that the expenditure is in order and complies with the provisions applicable and the principle of sound financial management has been applied. Monitoring will be ensured through indicators such as time to pay and budget implementation amongst others.

Ex-ante controls for Horizon Europe programme are implemented using the tools and methods developed by the European Commission.

Ex-post controls are an important tool to support management's assurance on the achievement of the financial management and internal control objectives.

Ex-post controls of operational expenditure will continue to be implemented in line with the Audit Strategy of Horizon Europe, which is an integral part of the overall Horizon Europe Control Framework. The Common Audit Service of the Common Implementation Centre of the Research & Innovation Directorate of the European Commission carries out all audits for Global Health EDCTP3 (internally or outsourced to external firms) for Horizon Europe. The first ex-post audit for Global Health EDCTP3 will be launched in 2025.

During 2026, the JU will continue to work with the Research and Innovation (R&I) family to implement the control strategy (ex-ante and ex-post) for the Horizon Europe programme.

2.5.3 Risk assessment and management

The risk assessment methodology aims to identify the main risks in achieving the objectives of the JU, analyse them and determine action plans on how they should be managed. All risks are captured in the Global Health EDCTP3 Risk Register, which provides for an evaluation of the risk level and description of the mitigating activities.

The annual risk assessment exercise took place between September and October 2025. The most significant risks were included in the risk register of Global Health EDCTP3. An action plan has been put in place and will be monitored and followed up regularly. The JU will continue to run an annual risk assessment exercise in 2026.

2.5.4 Anti-fraud initiatives

The R&I family has established a common implementation approach for the prevention and detection of fraud in the framework programmes. Global Health EDCTP3 alongside other entities implementing Research and Innovation Programmes share participants and face similar fraud patterns, making therefore the common approach more effective and efficient to coordinate anti-fraud activities. The Common Anti-Fraud Strategy in the research and innovation family was revised in 2023 and endorsed by the Horizon Europe Executive Committee on 22 December 2023. Global Health EDCTP3 adopted by analogy the Anti-Fraud strategy of the R&I family on 15 March 2024 (GH-EDCTP3-GB/09/2024).

In 2026, the specific Global Health EDCTP3 anti-fraud strategy will be implemented, covering also areas that are not related to grant management: such as, fraud risks related to procurement, expert management.

Further actions have been planned, such as:

- Awareness raising amongst staff on anti-fraud measures;
- Participation to meetings organised by DG RTD and common trainings organised for the JUs (in cooperation with the Common Audit Service).

2.5.5 Audits

Internal audits are carried out by the Internal Audit Service of the European Commission (IAS) in liaison with the Internal Control and Audit Manager. The IAS completed in 2025 an in-depth risk assessment to establish the strategic internal audit plan (SIAP) for Global Health EDCTP3 that allowed to identify an audit plan for the next three years, i.e. 2026-2028. The main activity for the year will focus on supporting IAS work on future audits launched for the JU.

External audits are carried by the European Court of Auditors (ECA). The ECA will audit and issue opinions on the legality and regularity of the underlying transactions, revenue, and reliability of accounts. In line with Articles 70(6) and 71 of the EU Financial Regulation, the audit of the reliability of the accounts of the JUs is outsourced to independent audit firms and ECA reviews the quality of the work done by these external firms and obtains sufficient assurance so that they can rely on their work in formulating ECA audit opinions on the reliability of the JUs annual accounts for the specific year. In this regard, the annual accounts are audited by an external audit company (contracted through Europe's Rail Joint Undertaking framework contract on statutory audit services).

In 2026, the key activities will focus on:

- Providing the necessary information and support for ECA audit in 2025 and 2026 accounts.
- Following up and implementing any audit observations identified during the ECA annual audit on Global Health EDCTP3 for the financial year 2024.

- Supporting the ECA team in their field or remote missions for the Global Health EDCTP3 projects selected (on a sample basis) for an ex-post financial review.
- Liaising with the external audit company that will audit the 2025 annual accounts, as required by the Financial Rules of Global Health EDCTP3.

The **Internal Audit Capability** of Global Health EDCTP3 is performed by the Internal Control and Audit Manager. The objective established for the Internal Audit Capability is to provide the Executive Director with assurance as to the effectiveness and efficiency of risk management, control and governance process in the JU.

3. Budget 2026

3.1 Global Health EDCTP3 budget 2026

In accordance with the General Annexes of the Horizon Europe Work Programme 2023-2025, regarding budget flexibility, the budgets set out in the calls and topics are indicative. Unless otherwise stated, final budgets may change following evaluation. In addition, the final figures may change by up to 20% compared to the total budget indicated in each individual part of the Work Programme. Changes within these limits will not be considered substantial within the meaning of Article 110(5) of Regulation (EU, Euratom) No 2024/2509.

Budget 2026 covers both administrative and operational requirements of the year.

It is noted that the budget of the JU shall be adapted to consider the amount of the EU contribution as laid down in the budget of the Union.

Revenue

The JU will be impacted by the reduction of budget following the contribution from the EU budget to the AI Giga Factories, which was confirmed by the European Commission for the years 2026 and 2027.

The detailed figures related to the reallocation of appropriations in Horizon Europe have been included in the proposal for the adoption of the EU budget 2026, and are reported below for Global Health EDCTP3:

AI Giga Factories contribution (Million EUR)	2026	2027	Total
Budget cut for Global Health EDCTP3	-4,538	-2,275	-6,813

These figures (including EFTA appropriations at the rate of 2.60%) mention for each JU the split by year between 2026 and 2027. The figures for 2026 will be included in the upcoming Amending Letter for the JU's budget procedure 2026 and should therefore be included into the present document.

The **Administrative budget** is financed by fresh appropriations under Horizon Europe. According to Article 102 of the Council Regulation 2021/2085[29], the European Union covers the entire administrative expenditure for the Global Health EDCTP3 JU.

The **Operational budget** breakdown is as follows:

- Horizon Europe operational contributions are financed by fresh appropriations of the EU. An additional amount of EUR 16.9 million from the EU funding is foreseen following the UK's association to Horizon Europe.
- EUR 8,948,016 of payment appropriations for the contribution of the EDCTP Association corresponding to the payment of the second instalment of the total EUR 11,948,016 of commitment appropriations signed in 2025.
- Reactivation of unused operational commitment appropriations from 2023 and 2024 amounting to EUR 2.5 million are included in the initial budget.

[29] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

- Reactivation of EUR 500,000 unused administrative commitment appropriations from 2025 is transferred to the operational budget 2026 with the objective to mitigate part of the impact of the budget reduction following the AI Giga Factories contribution.

Expenditure

Title 1 - Staff

Title 1 represents 68% of the total 2026 administrative budget. The principal allocation of this cost are the salaries and allowances for staff and external personnel (contract agents, interims and trainees) as presented in the establishment plan.

In addition, missions' cost is composed of an estimated amount of EUR 123,000 for the annual mission budget (which has significantly decreased compared to 2025 due to the attendance of the staff to the Twelfth EDCTP Forum in Kigali (Rwanda) last year.

On top of that, Title 1 also includes training for staff and other staff-related expenditure such as different SLAs signed with the EC (DG HR and PMO services among others), recruitment costs, European schools and other events and activities.

Title 2 - Infrastructure and operating expenditure

Title 2 represents the remaining 32% of the administrative budget for 2026.

It covers, amongst others, the rental and building costs of the new premises on the second floor at the White Atrium building. In particular, this important decrease of costs associated to rental of buildings is because last year there was a complete renovation of the HVAC system in the new offices.

ICT costs will increase compared to 2025.

Moreover, information and communication costs, current administrative expenditure (office supplies, library, translation services, etc.) and telecommunication and postage costs (telephony, videoconferencing, internet and postal services among others) will increase slightly compared to the previous year with the aim of signing new contracts.

Meeting expenses (caterings and other costs) for the organisation of the Governing Board, Scientific Committee and Stakeholders Group will increase in view of potential physical meetings in 2026.

Running costs in connection with operational activities will also include the reimbursement of experts, such as transportation and accommodation.

Service contracts generally cover contracting with third parties outside the European Commission's environment. There is a significant increase with the aim of signing new contracts and renewals in 2026.

Finally, other infrastructure and operating expenditure will include different services covered under the SLAs signed with the EC departments (DG DIGIT, BUDG, etc.) and other JUs or executive agencies.

Title 3 - Operational costs

Please refer to point *"3.4 Detailed overview of operational budget 2026"*.

3.2 Statement of revenue

STATEMENT OF REVENUE					
Budget line	Title Chapter	Adopted Budget - Financial Year 2026			
		Estimated Commitment Appropriations	In %	Estimated Payment Appropriations	In %
1	**EU contribution (excl. EFTA and third countries contribution)**	**135.211.301**	**85,1%**	**138.148.905**	**67,1%**
1000	*of which Administrative (Title 1&2)*	*6.762.044*	*4,3%*	*6.762.044*	*3,3%*
1100	*of which Operational (Title 3)*	*128.449.257*	*80,8%*	*131.386.861*	*63,9%*
2	**EFTA and third countries contribution**	**20.717.494**	**13,0%**	**58.647.871**	**28,5%**
2000	*of which Administrative (Title 1&2)*	*425.813*	*0,3%*	*425.813*	*0,2%*
2100	*of which Operational (Title 3)*	*20.291.681*	*12,8%*	*58.222.058*	*28,3%*
3	**Financial contribution from members other than the Union***	-	-	**8.948.016**	0
3100	*Of which Operational (Title 3)*	-	-	*8.948.016*	0
4	**Contributing Partners financial contribution**	-	-	-	-
4100	*of which Operational (Title 3)*	-	-	-	-
5	**Interest generated**	-	-	-	-
6	**Recoveries**	-	-	-	-
6000	*of which Administrative (Title 1&2)*	-	-	-	-
6100	*of which Operational (Title 3)*	-	-	-	-
7	**Other revenue****	**p.m.**	-	**p.m.**	-
7000	*of which Administrative (Title 1&2)*	-	-	-	-
7100	*of which Operational (Title 3)*	-	-	-	-
8	**Unused appropriations from previous years**	**2.978.623**	**1,9%**	-	-
8000	*of which Administrative (Title 1&2)*	*500.000*	*0,3%*	-	-
8100	*of which Operational (Title 3)*	*2.478.623*	*1,6%*	-	-
TOTAL ESTIMATED REVENUE		**158.907.418**	**100%**	**205.744.792**	**100%**

Table 4: Statement of revenue 2026

3.3 Statement of expenditure

STATEMENT OF EXPENDITURE			
Budget line	Title Chapter	Adopted Budget - Financial Year 2026	
		Estimated Commitment Appropriations	Estimated Payment Appropriations
TITLE 1 - Staff expenditure			
11	Salaries & allowances	4.387.000	4.387.000
1100	*of which establishment plan posts*	*3.217.000*	*3.217.000*
1110	*of which external personnel*	*1.170.000*	*1.170.000*
1300	Mission expenses	123.000	123.000
1500	Training	60.000	60.000
1900	Other staff related expenditure	300.000	300.000
Total Staff		4.870.000	4.870.000
TITLE 2 - Infrastructure and operating expenditure			
2000	Rental of buildings and associated costs	464.000	464.000
2100	Information, communication technology and data processing	400.000	400.000
2200	Office equipment (movable property and associated costs)	50.000	50.000
2300	Current administrative expenditure	70.000	70.000
2400	Postage and telecommunications	50.000	50.000
2500	Meeting expenses	50.000	50.000
2600	Running costs in connection with operational activities	30.000	30.000
2700	Information and publishing	450.000	450.000
2800	Service contracts	390.000	390.000
2900	Other infrastructure and operating expenditure	363.857	363.857
Total infrastructure and operating		2.317.857	2.317.857
TOTAL ADMINISTRATIVE (1+2)		7.187.857	7.187.857
TITLE 3 - Operational expenditure			
3000	Grants	148.878.000	195.715.374
3100	Experts costs	1.300.000	1.300.000
3200	Other operational costs	1.541.561	1.541.561
TOTAL OPERATIONAL (3)		151.719.561	198.556.935
TITLE 4 - Unused appropriations			
4000	Unused administrative appropriations	-	-
4100	Unused operational appropriations	-	-
TOTAL UNUSED (4)		-	-
TOTAL ESTIMATED EXPENDITURE		158.907.418	205.744.792

Table 5: Statement of expenditure 2026

3.4 Detailed overview of operational budget 2026

Year 2026	Type of action and topic	Value of the action (Million)
Multi-annual Call for Proposals	**Call 1 - RIA HORIZON-JU-GH-EDCTP3-2026-01-two-stage**	**88,9**
	Topic 1: *Global Collaboration Action for the development of TB drugs for therapy and chemoprophylaxis in adults and children in sub-Saharan Africa*	*30,0*
	Topic 2: *Global Collaboration Action for Prevention and treatment of Lower Respiratory Tract Infections (LRTIs) in sub-Saharan Africa*	*33,9*
	Topic 3: *Global collaboration action towards a better prevention, treatment and clinical management of HIV co-infections or co-morbidities in sub-Saharan Africa*	*25,0*
	Call 2 - RIA HORIZON-JU-GH-EDCTP3-2026-02-two-stage	**25,0**
	Topic 4: *Global Collaboration Action on climate and health in sub-Saharan Africa*	*25,0*
	Call 3 - CSA HORIZON-JU-GH-EDCTP3-2026-03-single-stage	**33,0**
	Topic 5: *Training networks for sustained capacity building related to ethics, regulatory and pharmacovigilance*	*15,0*
	Topic 6: *Enhancing Integrated Research and Healthcare in sub-Saharan Africa Through Digital Innovation and Artificial Intelligence in SSA*	*18,0*
Experts management costs	Including through REA	**1,3**
Other operational costs	Including Public Health Emergency (PHE), Expansion and consolidation of the EDCTP Knowledge Hub and the organisation of the EDCTP Forum 2027 in Madrid	**3,5**
TOTAL		**151,7**

Table 6: Detailed overview of operational budget 2026

Further information about the multi-annual call for proposals is available in the Annex 4.1.

It is to be noted that out of the EUR 153.3 million available for the operational commitment appropriations 2026, a reduction of EUR 4.5 million has been applied following the contribution from the EU budget to the AI Giga Factories and around EUR 2.5 million was de-committed in 2025 related to unused appropriations from previous Calls. On top of that, in order to mitigate part of the budget cut for the AI Giga Factories contribution, a transfer of EUR 500,000 unused administrative commitment appropriations has been made to operational budget 2026. This amount will be reactivated and directly reallocated to fund projects from the 2026 Calls.

Moreover, "Other operational costs" include EUR 1 million for a possible allocation to public health emergency action (PHE) and another EUR 1 million will be allocated to the Expansion and consolidation of the EDCTP Knowledge Hub.

Finally, the budget allocated to experts' management costs is EUR 1.3 million and around 1.5 million are included for the preparation of the EDCTP Forum 2027 in Madrid (Spain).

4. Annexes

4.1 Calls for proposals 2026 and other actions not subject to calls for proposals

4.1.1 Indicative operational budget 2026

Call	Type of Action	Indicative JU Budget (in million EUR)
HORIZON-JU-GH-EDCTP3-2026-01-two-stage (3 topics)	RIA	88.9
HORIZON-JU-GH-EDCTP3-2026-02-two-stage (1 topic)	RIA	25.0
HORIZON-JU-GH-EDCTP3-2026-03-single-stage (2 topics)	CSA	33.0
HORIZON-JU-GH-EDCTP3-2026-KHUB-01-IBA (1 topic)	IBA	1.0
Other Actions – Mobilisation of research funds in case of Public Health Emergencies	RIA or CSA	1.0
Other Actions – Experts (indicative in the current WP2026 version)	Expert contract action	1.3
Other Actions – Preparation of the EDCTP Forum 2027 in Madrid (Spain)	Public procurement	1.5
Overall indicative budget		**151.7**

Table 7: Indicative operational budget 2026 per call/action

4.1.2 Calls for proposals 2026

This is the fifth work programme under Global Health EDCTP3. The topics are based on the SRIA adopted by the Governing Board[30]. The Global Health EDCTP3 programme is implemented under the framework of the EU global health strategy[31] adopted in November 2022, the EU-AU summit deliverables[32] and the AU-EU innovation agenda launched in July 2023[33] and will play a key role in achieving the objectives of these strategies and initiatives.

Under this year's work programme, **three calls for proposals** are launched:

- HORIZON-JU-GH-EDCTP3-2026-01-two-stage covering three (3) topics for Research and Innovation Actions (RIA)
- HORIZON-JU-GH-EDCTP3-2026-02-two-stage covering one (1) topic for Research and Innovation Actions (RIA)

30 The Global Health EDCTP3 Strategic Research and Innovation Agenda
31 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
32 Sixth European Union - African Union Summit: A Joint Vision for 2030 - Consilium (europa.eu)
33 The AU-EU Innovation Agenda

- HORIZON-JU-GH-EDCTP3-2026-03-single-stage covering two (2) topics for Coordination and Support Actions (CSA)

The work programme also foresees other actions, including: (a) expansion and consolidation of the EDCTP Knowledge Hub and (b) funding to be mobilised in case of a public health emergency.

With the work programme 2026 we extend the range of topics addressed under Global Health EDCTP3, building on the EDCTP2 programme and Global Health EDCTP3 activities launched between 2022 to 2025. The work programme 2026 addresses several objectives within the scope of Global Health EDCTP3: this ranges from 1) the development of treatment and prevention tools for TB, LRTIs, co-infections/co-morbidities to HIV, and climate-change driven infectious diseases, 2) capacity strengthening activities through training networks focussing on ethics, regulatory and pharmacovigilance, and 3) digital innovation and Artificial Intelligence (AI) to enhance integrated research and healthcare in SSA.

For all topics in the work programme, where relevant, the support to African scientists from junior researchers to senior researchers in clinical research that embraces hands-on-training and mutual bi-directional learning during implementation of research projects should be promoted to assist them in sustaining and/or advancing their scientific careers. These scientists should be selected keeping gender and regional balance in mind.

The support through topics targeting a particular disease area as defined in the work programme 2026 complements support provided through broader topics under the previous work programmes of Global Health EDCTP3[34].

4.1.2.1. Conditions to the calls and call management rules

A. For topics requiring clinical studies

In the context of this work programme, a clinical study covers clinical studies/trials/investigations/cohorts and is defined as any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes, but it is not limited to clinical studies, as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on *in vitro* diagnostic medical devices)[35].

For single-stage proposals and full proposals of two-stage proposals, the use of the “Information on clinical studies” template is recommended:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

Three mandatory deliverables should be included in the single-stage proposals or full proposals of two-stage proposals involving clinical studies to the extent relevant depending on the stage of the study:

1. **Study initiation package (before enrolment of the first study participant) including**

[34] Tuberculosis, emerging infectious diseases as well as HIV/AIDS, Malaria and neglected infectious diseases have all been addressed through projects funded from previous calls.

[35] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

- Registration number of the clinical study in a registry meeting WHO Registry criteria[36];
- Final version of study protocol as approved by the regulator(s)/ethics committee(s);
- Regulatory and ethics (if applicable, institutional) approvals required for the enrolment of the **first study participant.** (In case of **multicentre clinical studies**, submission of approvals for the first clinical site is sufficient.)

2. Midterm recruitment report

This report is due when 50% of the study population is recruited. The report shall include an overview of the number of recruited participants by clinical sites, any problems in recruitment and, if applicable, a detailed description of implemented and planned measures to compensate for any incurred delays.

3. Report on the status of posting results

Irrespective of the successful completion of the clinical study, summary results must be posted in the applicable registry/ies (where the study was registered) even if the timing of posting of results falls outside of the grant agreement period. The report is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

Studies must be registered in a registry meeting WHO Registry criteria[37] before recruitment of the first subject. From 31 January 2023, all initial clinical trial applications in the European Union must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. All ongoing clinical trials in EU must be transitioned to CTIS by 30 January 2025.[38]

The applicants should ensure that the sample size of the clinical studies is relevant to obtain meaningful results.

Proposals should include one or more clinical trial(s) to be conducted in SSA. The clinical trial(s) must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level.

[36] https://www.who.int/clinical-trials-registry-platform/network/registry-criteria
[37] https://www.who.int/clinical-trials-registry-platform/network/registry-criteria
[38] https://www.ema.europa.eu/en/news/use-clinical-trials-information-system-becomes-mandatory-newclinical-trial-applications-eu

4.1.2.2 Budget for calls for proposals

Indicative budget per topic

Call	Topic	Type of Action	Indicative JU Budget (in million EUR)	Expected JU contribution per project (in million EUR)	Number of projects expected to be funded
HORIZON-JU-GH-EDCTP3-2026-01-two-stage (3 topics)	**HORIZON-JU-GH-EDCTP3-2026-01-TB-01-two-stage:** Global Collaboration Action for the development of TB drugs for therapy and chemoprophylaxis in adults and children in sub-Saharan Africa	RIA	30.0	10	3
	HORIZON-JU-GH-EDCTP3-2026-01-LRTI-02-two-stage: Global Collaboration Action for Prevention and treatment of Lower Respiratory Tract Infections (LRTIs) in sub-Saharan Africa	RIA	33.9	8.475	4
	HORIZON-JU-GH-EDCTP3-2026-01-HIV-03-two-stage: Global collaboration action towards a better prevention, treatment and clinical management of HIV co-infections or co-morbidities in sub-Saharan Africa	RIA	25.0	5.0	5
HORIZON-JU-GH-EDCTP3-2026-02-two-stage (1 topic)	**HORIZON-JU-GH-EDCTP3-2026-02-CH-01-two-stage:** Global Collaboration Action on climate and health in sub-Saharan Africa	RIA	25.0	5.0	5
HORIZON-JU-GH-EDCTP3-2026-03-single-stage (2 topics)	**HORIZON-JU-GH-EDCTP3-2026-03-SERP-01:** Training networks for sustained capacity building related to ethics, regulatory and pharmacovigilance	CSA	15.0	1.5	10
	HORIZON-JU-GH-EDCTP3-2026-03-DIGIT-02: Enhancing Integrated Research and Healthcare in sub-Saharan Africa Through Digital Innovation and Artificial Intelligence in SSA	CSA	18.0	2.25	8
	Overall indicative budget		**146.9**		

Table 8: Indicative budget 2026 per topic

4.1.2.3 General conditions related to this work programme

For call management, Global Health EDCTP3 will utilise the EC eGrants IT systems available under the EU Funding & Tenders Portal. Unless specified otherwise, the sections of the General Annexes to the Horizon Europe Work Programme[39] apply *mutatis mutandis* to the calls for proposals covered by this Global Health EDCTP3 work programme.

General conditions related to Global Health EDCTP3 calls with indication of specific conditions	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B except for the specific conditions for the Global Health EDCTP3 funding as regards entities eligible for funding and consortium composition, the specific rule for countries where the coordinator may be established and the obligation to designate a scientific project leader as established below in Section 4.1.2.4.
Financial and operational capacity and exclusion criteria	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D. Also, **for the three (3) topics under call HORIZON-JU-GH-EDCTP3-2026-01-two-stage and the one (1) topic under call HORIZON-JU-GH-EDCTP3-2026-02-two-stage,** additional aspects on award criteria apply. The scores and weighting section for single stage evaluations as well as second stage of two-stage evaluations, for both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA) are set out below.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G and specific conditions regarding application of the right to object apply as described below. **For the three (3) topics under the call HORIZON-JU-GH-EDCTP3-2026-01-two-stage and for the one (1) topic under HORIZON-JU-GH-EDCTP3-2026-02-two-stage,** specific conditions regarding affordable access apply. **For the two (2) topics under call HORIZON-JU-GH-EDCTP3-2026-03,** specific conditions regarding use of lump sum contributions [as defined in the Decision of 7 July 2021

[39] wp-13-general-annexes_horizon-2023-2024_en.pdf (europa.eu)

	authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027)][40] apply. **For the one (1) topic HORIZON-JU-GH-EDCTP3-2026-03-SERP-01**, specific conditions regarding financial support to third parties' conditions also apply. The conditions are spelled out under the respective topics as relevant.

More common conditions for all topics

1. FAIR data principles and open access of publications are required in line with the Model Grant Agreement[41]. In the context of this work programme, FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability. Data can include exploitation of information and data from European data infrastructures and programmes such as Copernicus, European Space Agency, and the GEO initiative. For further details, see the FAIR principles website[42], the FAIR cookbook[43] and the guides for researchers on how to make your data FAIR[44]. Data quality and integration as well as issues of cybersecurity and data protection must be addressed. Use of explainable and transparent AI tools[45] in all research is encouraged where appropriate.
2. The proposals should put emphasis on ethically involving vulnerable groups, including participants from less-resourced, underserved, or hard-to-reach communities in SSA. Applicants are also encouraged to provide methodologies for translating research findings into public health practice and policy guidelines. The applicants are encouraged to consider the latest innovations and advances in the clinical trial design and research methods in order to evaluate promising interventions allowing shorter development timing.
3. As relevant, the proposals should involve all stakeholders, most notably policy makers, public health authorities, health care professionals and end-users. The applicants must ensure strong community engagement. International cooperation is encouraged, and the proposed research is expected to be multidisciplinary.
4. Proposals are expected to come from research consortia with a strong representation of institutions and researchers from SSA countries, including involvement of Franco/Lusophone countries where possible and relevant. Proposals are to foster inclusive equitable partnerships also considering institutions or organisations from countries with high burden of disease and relatively lower research capacities, to the extent possible.
5. Where relevant, it will be important for proposals to show in their dissemination and exploitation plans consideration and support to the existing and emerging partnerships between the EU/Team Europe (EU institutions, Member States and EU Financing Institutions) and the African Union (AU) and their key agencies, notably the AU-EU Health Partnership hubs (Manufacturing and

[40] This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu)

[41] unit-mga_he_en.pdf (europa.eu)

[42] https://www.go-fair.org/fair-principles/

[43] https://faircookbook.elixir-europe.org/content/home.html

[44] https://www.openaire.eu/how-to-make-your-data-fair

[45] See: European strategic research agenda in artificial intelligence: https://www.elise-ai.eu/work/agendaand-programs

Access to Vaccines, medicines and health technologies (MAV+)[46], Sustainable Health Security[47], Public Health Capacity[48], Digital Health[49]) and align with the Africa CDC Strategic Plan 2023-2027[50] and the African Medicines Agency. Moreover, collaborations with the African Regional Intellectual Property Organisation[51] (ARIPO) and the African Intellectual Property Organisation (OAPI)[52] should also be fostered as well as strengthened promoting the development and assessment of innovative tools.

6. It will also be important that the projects arising from this call will contribute to the implementation of the short-term and medium-term actions of the AU-EU Innovation Agenda[53] in the area of Public Health and the EU global health strategy[54].
7. As part of the evaluation of the criterion “Excellence”, proposals for RIA actions must clearly demonstrate their added value beyond the state of the art within their respective areas complementing existing research and funding and building on past programmes and projects financed by the EDCTP Association and/or other funders, in line with Article 100 of the Council Regulation 2021/2085[55].
8. Proposals must comply with all ethics requirements arising out of the research, in line with Article 112 of the Council Regulation 2021/2085[56]. Proposals evaluated above threshold and considered for funding will undergo an ethics screening carried out by independent ethics experts. The ethics appraisal process focuses on the compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorisations and ethics approvals, proportionality of the research methods, and the applicants' awareness of the ethical aspects and social impact of their planned research.
9. The proposals should take into consideration the potential impact of clinical research activities on climate change and must take appropriate measures to minimise any potential negative effects.
10. Of note, despite blind evaluation being mentioned in the standard application form for stage 1 proposals of the two-stage calls available in the Funding and Tenders Portal (at the stage of adoption of this Work Programme), please note that the calls included in this WP are not part of the ‘blind evaluation pilot’, therefore no anonymisation is required for stage 1 proposals of the two-stage calls.

46 Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (europa.eu)
47 Sustainable Health Security - Africa | Capacity4dev (europa.eu)
48 Public Health Capacity - Africa | Capacity4dev (europa.eu)
49 Digital Health - Africa | Capacity4dev (europa.eu)
50 Africa CDC Strategic Plan 2023 – 2027 – Africa CDC
51 African Regional Intellectual Property Organization (ARIPO)
52 African Intellectual Property Organization (OAPI)
53 https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf
54 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
55 Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17–119.*
56 Ibid.

4.1.2.4 Specific conditions to Global Health EDCTP3

Specific conditions replacing the relevant sections in General Annex B to the Horizon Europe Work Programmes

A. Entities eligible for funding

This section applies to both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA).

To become a beneficiary, legal entities must be eligible for funding. To be eligible for funding, applicants must be established in one of the following countries:

- The Member States of the European Union, including their outermost regions: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden;
- The Overseas Countries and Territories (OCTs) linked to the Member States: Aruba (NL), Bonaire (NL), Curação (NL), French Polynesia (FR), French Southern and Antarctic Territories (FR), Greenland (DK), New Caledonia (FR), Saba (NL), Saint Barthélemy (FR), Sint Eustatius (NL), Sint Maarten (NL), St. Pierre and Miquelon (FR), Wallis and Futuna Islands (FR);
- Countries associated to Horizon Europe[57]: Albania, Armenia, Bosnia and Herzegovina, Canada (associated to Pillar II 'Global Challenges and European Industrial Competitiveness', including for the institutionalised European partnerships, and for award procedures implementing Union budget for the year 2024 and onwards), Faroe Islands, Georgia, Iceland, Israel, Kosovo[58], Moldova, Montenegro, New Zealand (associated to Pillar II 'Global Challenges and European Industrial Competitiveness' as from the Work Programmes 2023 onwards, including for the institutionalised European partnerships), North Macedonia, Norway, Serbia, Republic of Korea (Pillar II only), Switzerland, Tunisia, Turkey, Ukraine, United Kingdom;
- Until association agreements start producing legal effects either through provisional application or their entry into force, transitional arrangements apply. The transitional arrangements apply, at the time of the adoption of this Work Programme, with regard to the following countries and legal entities established in these countries, with which association negotiations are being processed or where association is imminent): Egypt, Morocco.
- The following countries which are constituent states of the EDCTP Association[59]: Benin, Burkina Faso, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Eswatini, Gabon, The Gambia, Ghana, Guinea-Bissau, Guinea-Conakry, Kenya, Liberia, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Republic of the Congo, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, Tanzania, Uganda, Zambia, Zimbabwe.

Legal entities which are established in countries not listed above (including in low-and middle-income countries that are not members of the EDCTP Association) will be eligible for funding if provided for in

[57] The list is correct at the time of adoption of this work programme. Please see the Horizon Europe List of Participating Countries on the Funding & Tenders Portal for up-to-date information on the current list and on the position for Associated Countries: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

[58] This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

[59] The list is correct at the time of adoption of this work programme. For an update, please check the EDCTP Association website www.edctp.org.

the specific call topic conditions, or if their participation is considered essential for implementing the action by the granting authority.

B. Consortium composition

Unless otherwise provided for in the specific call conditions, for all actions, due to the policy objectives of Global Health EDCTP3, legal entities forming a consortium are eligible to participate in actions under the programme provided that the consortium includes as beneficiaries:

- At least three legal entities independent from each other and each established in a different country, where legal entities are eligible to receive funding;
- At least one independent legal entity established in a Member State, or in an associated country to Horizon Europe that is a member of the EDCTP Association; and
- At least one independent legal entity established in a sub-Saharan African country that is a member of the EDCTP Association.

This condition applies to both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA).

For the two CSA (2) topics under call HORIZON-JU-GH-EDCTP3-2026-03 in case the applicant consortia opt for including the EDCTP Association as coordinator, the EDCTP Association must not be counted as one of the three independent legal entities necessary to ensure the eligibility of the consortium composition.

Specific cases:

Affiliated entities — Affiliated entities are eligible for funding under the same conditions as beneficiaries.

Associated partners — Entities not eligible for funding and therefore not able to participate as beneficiaries or affiliated entities (i.e. entities which participate in the action without signing the grant agreement, and without the right to charge costs or claim contributions) are allowed, subject to any conditions regarding associated partners set out in the specific call conditions.

International organisations – International European research organisations are eligible to receive funding. Other international organisations are not eligible to receive funding unless their participation is considered essential for implementing the action by the granting authority. International organisations with headquarters in a Member State or associated country are eligible to receive funding when provided for in the specific call conditions.

Specific rules regarding legal entities that may be the coordinator of an indirect action

In accordance with Article 110(2) of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[60], where entities established in a third country without an agreement to protect the financial interests of the Union participate with funding in an indirect action, the coordinator of the indirect action must be established in a Member State or associated country, or South Africa.

[60] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17–119*.

Scientific project leader

If the coordinator is not established in a country in SSA (*please see previous paragraph*), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described below is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity. The scientific project leader oversees the project scientific governance and leadership. For this purpose, proposals must include a work package where the details of scientific project leadership are laid down. The scientific project leader should indicatively perform the following tasks:

- During the call for proposals and selection process, coordinate meetings on and drafting of the full project proposal.
- Work with the coordinator and other beneficiaries on the drafting and negotiation of the consortium agreement and other legal agreements among the beneficiaries.
- Act as the key contact point for the Global Health EDCTP3 JU regarding all scientific action governance issues, steer and provide oversight in the development of the scientific actions, without prejudice to the tasks entrusted directly to the coordinator as per the Model Grant Agreement.
- Support and collaborate with the coordinator on its monitoring activities and the adoption of appropriate internal measures, to ensure that beneficiaries are fulfilling their obligations regarding budget, timeline, deliverables, and scientific quality.
- Review the action's deliverables and reports before their submission by the coordinator.
- Lead the work packages(s) related to the tasks of scientific project leadership.

Annex 1 to the grant agreement and the consortium agreement should address the relationship of the scientific project leader with the coordinator regarding their respective tasks, for example sharing of the information received from or sent to Global Health EDCTP3 on all issues of interest for the proper scientific management of the action.

C. Specific conditions related to scores and weighting

Replacing the scores and weighting section in General Annex D to the Horizon Europe Work Programmes as regards second stage of two-stage evaluations, for Research and Innovation Actions (RIA). Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the table. For full applications, each criterion will be scored out of 5. The threshold for individual criteria 1 (Excellence) and 2 (Impact) will be 4 and for criterion 3 (Quality and Efficiency of the implementation) will be 3. The overall threshold, applying to the sum of the three individual scores, will be 12.

Proposals that pass the individual threshold and the overall threshold will be considered for funding, within the limits of the available call budget. Other proposals will be rejected.

Nota bene: for the CSAs and the first stage of the two-stage evaluation of RIAs, the scores and weighting as indicated in Annex D of the General Annexes of the Horizon Europe work programme 2023/2025 apply.

D. JU right to object to transfer/exclusive licensing

Global Health EDCTP3 may, up to four (4) years after the end of the action, object to a transfer of ownership or to the exclusive licensing of results, as set out in the specific provision of Annex 5 of the

Model Grant Agreement. In addition, in accordance with Article 24(3) of Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[61] and the Model Grant Agreement, the right to object applies also to participants that have not received funding from the JU.

E. Information sharing regarding the proposals and the evaluation results

Applicants should be aware that the following information regarding their proposals may be shared with the members of the JU Committee of the EDCTP Association:

1. Following eligibility check of the applications: aggregated country level data i.e. number of applicants, funding requested, organisation type;
2. For successful proposals, following Global Health EDCTP3 Governing Board decision on the call evaluation results: number; acronym; title; duration; role; country; legal name; PIC; legal type; total cost; requested JU contribution;
3. Regarding project information following Grant Agreement (GA) signature: signature date of the GA; number, acronym, title, and duration of projects; role, country, legal name, PIC, legal type, URL, total cost, requested JU contribution, FC received, FC given, and IKOP of participants;
4. Under specific conditions and following Global Health EDCTP3 Governing Board approval of the request of EDCTP Association, for proposals on the reserve list and unsuccessful proposals: number; acronym; title; duration; role; country; legal name; PIC; legal type; total cost; requested JU contribution.

F. Access to information and involvement of contributing partners

Evaluation

To promote transparency and accountability, Global Health EDCTP3 may invite any contributing partners providing financial contributions under a certain topic to propose one representative as observer to participate in the evaluation process under confidentiality safeguards. This possibility does not apply to contributing partners that are part of a consortium submitting a proposal under the relevant topic.

Documents and information

By applying under any topic, participants consent that the JU reserves the right to share information and documents relevant to their application and where applicable their grant agreement and its implementation with contributing partners as identified and providing financial contributions under the relevant topic. This information and documentation will only be shared under confidentiality safeguards for policy and monitoring purposes. They include:

- Project proposals;
- Project results;
- Project reports;
- Project deliverables;

[61] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17*.

- Audit reports.

Global Health EDCTP3 may consult the relevant contributing partners for the purpose of assessing the project reports and deliverables.

4.1.3 General presentation of the 2026 calls for proposals

During 2026, Global Health EDCTP3 will launch two two-stage and one single stage open and competitive calls for proposals. These are planned as indicated in the table below.

Topics under Call	Type of Action	Call opening	Submission deadline short proposal	Submission deadline full proposal
HORIZON-JU-GH-EDCTP3-2026-01-two-stage (3 topics)	RIA	January 2026	March 2026	September 2026
HORIZON-JU-GH-EDCTP3-2026-02-two-stage (1 topic)	RIA	January 2026	March 2026	September 2026
HORIZON-JU-GH-EDCTP3-2026-03 (2 topics)	CSA	January 2026	Not applicable [62]	September 2026

Table 9: Indicative calls 2026 planning

Conditions for these three calls

Expected impact:

Activities funded under the Global Health EDCTP3 2026 work programme calls for proposals should contribute to:

1. achieving the reduction of disease burden of Tuberculosis, Lower Respiratory Tract Infections, HIV co-infections and co-morbidities and climate-change driven vector- and water-borne pathogens in the scope of the Global Health EDCTP3 SRIA, in SSA through increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investment;
2. establishing a resilient and future-ready regulatory environment, through strategic capacity building, digital transformation, and cooperation in SSA;
3. strengthening clinical human capital base in R&I, enhancing talent retention, knowledge sharing of best practices within the research and innovation landscape, accelerate integration of tools into health systems, accelerate scalable expansion and scaling up on innovations;
4. improving equity, access and inclusion across Global Health EDCTP3-funded projects;
5. developing capacity at clinical research centres;
6. improving support for community engagement in research.

[62] In a single stage call applicants submit only a full proposal.

Proposals are invited for the following topics:

HORIZON-JU-GH-EDCTP3-2026-01-TB-01-two-stage: Global collaboration action for the development of TB drugs for therapy and chemoprophylaxis in adults and children in sub-Saharan Africa

Type of action: Research and Innovation Action (RIA)

EU budget: EUR 30 million (to support up to 3 projects)

Background

Tuberculosis (TB) remains a prominent global health challenge. According to the WHO's Global TB Report 2024, the global rise in the number of TB incident cases, likely as effect of the disruption of TB services during the COVID-19 pandemics, has slowed and started to stabilise. The total number of people infected with TB was 10,8 million in 2023, a small increase from 10,7 million in 2022 although still much higher than 10,4 million in 2021 and 10,1 million in 2020. Globally, 80% of the number of deaths by TB occurred in the WHO African and South-East Asia regions, with 16 out of 30 countries located in sub-Saharan Africa (SSA). Most of the TB deaths among people with HIV occurred in the African Region. Adolescents and adults account for over 80% of the TB burden and are the main source of transmission, including transmission to children.

Millions of people affected by TB are missing out on quality care each year, including on access to affordable diagnostic tests and treatment, especially in low- and middle-income countries. TB affects populations inequitably and contributes to the cycle of ill health and poverty, with malnutrition currently being the most prevalent contributor to the incidence of TB and inadequate living conditions contributing to the spread of *M. tuberculosis* and its impact on the community. Investments in building robust, integrated, and resilient health systems, including in TB prevention, detection and treatment services and research and development infrastructure and community responses can advance universal health coverage and contribute to effective prevention and response. It is urgent to scale up comprehensive efforts to close long-standing gaps in prevention, diagnosis, treatment, and care of people at risk of TB, including children and immune-compromised individuals.

In terms of TB research and innovation, the following fields should be prioritised for TB drugs for therapy, chemoprevention or chemoprophylaxis according to the WHO Global TB Report 2024: new preventive drug treatments to prevent the progression to TB disease including patients with latent TB infection, and simpler, shorter treatments for TB disease.

Ongoing TB therapeutics trials are targeting particularly multidrug-resistant tuberculosis (MDR-TB), exploring promising agents as well as the potential of host-directed therapies. Various combination regimens with new or repurposed drugs, as well as host-directed therapies, are in Phase II or Phase III/IV trials. In Phase II, more than 25 trials are ongoing mainly addressing new drugs, shorter therapeutics regimens, MDR-TB and extensively-drug resistant TB (XDR-TB), and novel combinations. Several other challenges including long treatment regimens and adverse side effects need to be addressed.

TB and leprosy are both caused by mycobacteria being *Mycobacterium tuberculosis* and *M. leprae* respectively and share similar challenges related to transmission, diagnosis, and prevention in (co-) endemic settings. Post-Exposure Prophylaxis (PEP) has emerged as a promising intervention to prevent disease progression in individuals at risk due to potential infection, particularly in close contacts. Recognising the often-overlapping endemic areas, needs, tools and approaches in TB and

leprosy prevention, intervention studies are needed of integrated approaches that may offer an efficient way to address both diseases simultaneously. Several promising TB drugs have also shown activity against *Mycobacterium leprae*, showing potential for a unified PEP strategy preventing both diseases.

Expected outcome

The proposals submitted under this topic should aim to deliver results that are directed, tailored towards and contributing to improve TB-related outcomes in adults, and/or children in SSA.

In addition, proposals are also expected to lead to reduced burden of disease related to MDR-TB and XDR-TB and/or improved TB interventions in the most vulnerable populations, particularly children.

Scope

Proposals submitted under this topic should address the following points:

- Advance the clinical development by generating clinical data (Phase IIa trials and beyond) to progress towards registration of new TB drugs, improved or shorter therapeutics TB regimens, chemoprophylaxis and/or more comprehensive interventions combining therapeutics and chemoprophylaxis.

In addition, proposals submitted under this topic are also encouraged to:

- Generate clinical data with a focus on priority populations, including women of childbearing potential and pregnant women, and particularly children, especially for assets in late-stage development.
- Generate clinical data progressing development of new or improved treatment regimens for MDR-TB and XDR-TB.

Pulmonary TB disease, extrapulmonary TB forms, latent TB, DR TB, MDR TB, and XDR TB are considered in scope for this topic. Combination of chemoprophylaxis with vaccines, and combination of chemoprophylaxis with host-directed therapies are in scope as well.

For proposals developing treatment of latent TB, focus should be on individuals with increased risk of progressing to active disease. Proposals can address co-infections or co-morbidities of TB, including HIV/AIDS, but not as the primary objective of the proposal.

Sex/gender differences and the effects of age should be duly taken into account when relevant. For Phase III studies, applicants are encouraged to ensure an adequately statistically powered study allowing for sex/gender and age specific analysis when relevant.

Treatment decision algorithms can be included but not as the primary objective of the proposal.

It is highly important to implement solutions as soon as possible. The granting authority will therefore base its funding decision relevant to this topic on the ranking of the proposals considering a portfolio approach taking into account late stage (phase III) proposals versus valuable more early-stage proposals, all graded above the threshold.

The development of prophylactic vaccines, diagnostics and monoclonal antibodies, Phase I a/b clinical trials of single and/or combination drugs, and implementation research in early phase studies are **not in scope**.

Preclinical studies are considered out of scope of the topic.

However, preparatory activities conducted during the preclinical phase can be considered in scope if they enable the conduct of the clinical study/ies in scope (these activities include but are not limited to protocol writing, development/evaluation of laboratory tests, Chemistry, Manufacturing, and Controls (CMC) related activities, etc.).

For all Global Collaboration Actions such as this topic, proposals submitted are expected to leverage financial and/or in-kind contribution from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners. Each contribution should be well described and budgeted in each proposal, so that the activities and related costs that are covered by the in-kind or financial contribution(s) are clearly identified.

Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation. and an access strategy that will allow patients in low-resource settings to access the final product.

The applicants are encouraged to consider the latest innovations and advances in the clinical trial design and research methods to evaluate promising interventions allowing shorter development timings. Applicants are also encouraged to follow the WHO Guidance for best practices for clinical trials.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers or clinical Investigators, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines and are encouraged to follow guidance provided in the EDCTP Knowledge Hub Research into Policy Toolkit.

Where possible and relevant, collaboration and coordination with the AU-EU Health Partnership's – Manufacturing and Access to Vaccines, medicines and health technologies (MAV+) hub or similar African initiatives is encouraged. The applicants could show, for example, willingness to enter into technology transfer agreements with their counterparts - including the provision of patents, technical knowledge and know-how, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from SSA countries, including active participation of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to institutions/organisations in countries with high disease burden but with relatively lower research capacities.

Post-Exposure Prophylaxis (PEP) research – leprosy focus

In the context of studies on TB post-exposure prophylaxis, the Leprosy Research Initiative will co-fund one or more projects also targeting leprosy post-exposure prophylaxis (PEP), for instance, through integrated implementation of PEP or by evaluating or validating a uniform PEP regimen for both diseases in a clinical trial. The objective and funding of the leprosy-related objective is to be included in the proposal with a total indicative JU budget of 5 million EUR. The selected project(s) will contribute to advancing knowledge and strategies for PEP in the context of TB and leprosy, aligning with broader institutional goals in infectious disease control.

Expected impact

The actions funded under this topic should contribute to achieve the reduction of disease burden in SSA through increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investment.

Proposals are expected to include the effective in-kind and/or financial contribution of contributing partners, in order to produce more meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation (EU) 2021/2085[63]). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit a first draft of the endorsement letter to the Programme Office before the deadline for submission of the second-stage applications[64]. For details on the process on becoming a Global Health EDCTP3 contributing partner, please consult the Guide for contributing partners.

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate i.e. as beneficiaries or affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement. Also, Global Health EDCTP3 contributing partners can be a country, an international organisation or any public or private legal entity, other than the Global Health EDCTP3 members or their constituent or affiliated entities (please consult the Guide for contributing partners).

Specific conditions to the topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 10 million per project to be matched by an equal or greater financial and/or in-kind contribution from contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 30 million.
Type of action	Research and Innovation Action (RIA)
Award criteria	In addition to the aspects of award criteria included in General Annex D, the following aspects are taken into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant research activities via

[63] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

[64] The Global Health EDCTP3 Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 website or is missing any compulsory elements. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 Governing Board.

	the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of the implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085[65], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results[66] an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). The plan is to be submitted with the second-stage proposal. In addition to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.

65 Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17*.

66 For more information on the Plan for the exploitation and dissemination of results, please consult the General Annexes of Horizon Europe Work Programmes.

Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085[67], participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

[67] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

Global Health
EDCTP3

Co-funded by the European Union

HORIZON-JU-GH-EDCTP3-2026-01-LRTI-02-two-stage: Global collaboration action for prevention and treatment of Lower Respiratory Tract Infections (LRTIs) in sub-Saharan Africa

Type of action: Research and Innovation Action (RIA)

EU budget: EUR 33.9 million (to support up to 4 projects).

Background

Lower respiratory tract infections (LRTIs) are a leading cause of morbidity and mortality in Sub-Saharan Africa (SSA), particularly among children under five years, the elderly, and immunocompromised individuals. LRTIs is among the top four causes of mortality despite the existence of vaccines against many of their aetiologies suggesting that deaths are largely preventable.

From a prevention perspective, numerous areas require improvement. Awareness about preventive measures such as improved sanitation, better air quality, and reducing indoor air pollution are essential, especially in children. Other vital components for combating the spread of LRTIs are public health education campaigns focusing on hygiene practices, breastfeeding as well as vaccination and the importance of early medical intervention.

Vaccines against pneumococcal disease, influenza, and respiratory syncytial virus (RSV) have proven effective in reducing LRTI-related hospitalizations and deaths in other regions in the world. However, access to vaccines and coverage of these vaccines in SSA is insufficient due to financial and logistical barriers. A single-dose monoclonal antibody (mAb) that provides season-long protection against RSV was approved in EU in 2022. However, several barriers preclude the successful delivery of the mAb in LMICs, including low awareness and accessibility of the mAbs, including the costs of mAbs. The assessment of barriers—financial, logistical, and other—remains a fundamental challenge in achieving optimal vaccine coverage in SSA.

Treatments such as antivirals and low-cost monoclonal antibodies can prevent death once an individual is infected, yet accessibility is to be improved for those in need. To better target the treatment avoiding overuse of antibiotics, it is also important to have rapid diagnostics available, accessible and affordable.

Addressing LRTIs in the region requires targeted multifaceted strategies that consider local challenges such as limited healthcare access, high disease burden other infectious diseases like HIV and malaria, and antimicrobial resistance. Improving access to quality healthcare is critical. Many rural areas in SSA face shortages in healthcare workers and medical supplies, making timely diagnosis and treatment of LRTIs challenging. Strengthening healthcare systems, increasing the availability of essential medications (such as antibiotics for bacterial infections and oxygen therapy for severe cases), and ensuring consistent access to the appropriate vaccines.

Country-level strategies and work plans, coordination of the interventions, critical partners engagement, and promotion of the innovations to overcome the barriers to service delivery are recommended by the Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) to governments and partners in order to reduce the mortality from LRTIs (especially in children) and its incidence, following the Protect-Prevent-Treat strategy.

Expected outcome

The proposals submitted under this topic should aim to deliver results that are directed, tailored towards and contributing to strengthening the capacity of SSA health actors to address LRTIs, associated complications and barriers to effective management.

In addition, proposals are also expected to lead to:

1. improved LRTI-related outcomes, including mortality and morbidity in SSA and/or
2. increased access to LRTI interventions in SSA.

Scope

Proposals submitted under this topic should carry out late-stage clinical studies (Phase IIb and after) advancing prevention and treatment of pathogens related to Lower respiratory tract infection (LRTI) by evaluating the safety, immunogenicity, efficacy and/or effectiveness of approved or novel preventive or therapeutic candidates targeting individuals in SSA.

The proposals submitted under this topic should address at least one of the following points:

1. Obtain evidence of immunogenicity, efficacy, safety or clinical utility on new or existing preventive measures against LRTI pathogens listed below, or
2. Obtain evidence of efficacy, safety or clinical utility on new or existing treatment measures against LRTI pathogens listed below.

In addition, the proposals submitted under this topic should include at least one of the following:

1. Obtain evidence on new or existing preventive health solutions against LRTI for children (including maternal vaccination).
2. Improvement of preventive and/or treatment measure's coverage, access, scaling-up and/or availability.
3. Implementation of existing intervention with demonstrated efficacy and safety in other regions, with generation of data on real-world effectiveness and cost-effectiveness.
4. Generate clinical data on host-strengthening interventions (non-specific effects of live attenuated vaccines, pre/probiotics, and/or other non-pharmaceutical interventions).

Applicants are encouraged to focus on interventions that could become available to patients as soon as possible, as assets in phase III and interventions already approved in EU/US.

Clinical studies and implementation research if any, of interventions already approved in EU and/or US should be designed fit-for-purpose, generating the data as needed to ensure the implementation of interventions in SSA.

Pathogens in scope of the topic are: *S. pneumoniae*, *H. influenzae*, *S. aureus*, and *K. pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumoniae,* human respiratory syncytial virus (RSV), adenovirus, rhinovirus/enterovirus, influenza A/B, human parainfluenza viruses, and human metapneumovirus. Pathogens/disease that are considered out of scope are *Mycobacterium tuberculosis*/Tuberculosis, Cytomegalovirus (CMV), human coronaviruses and fungi.

Prophylactic vaccines, monoclonal antibodies and antiviral therapeutics (excluding antibiotics) are in scope. Proposals evaluating monoclonal antibodies should aim to increase accessibility by reducing the cost of production enabling a lower purchase price.

Implementation research to enable global access of the interventions by addressing cost effectiveness analysis and/or assessing barriers for access and health system integration, is in scope. In addition,

proposals including implementation research are encouraged to consider rural and remote areas as well as informal urban settlements.

Sex and gender differences and the effects of age should be duly taken into account when relevant. For Phase III studies, applicants are encouraged to ensure adequate statistical power for sex/gender- and age-specific analyses as relevant.

Activities which are encouraged to be included in the proposals are: generating evidence on new or existing preventive health solutions against LRTI targeting specifically children, activities that lead to the improvement of the uptake, access, scaling-up and/or availability of the health solutions, implementation of existing intervention with demonstrated efficacy and safety in other regions, with generation of data on real-world effectiveness and cost-effectiveness, activities that combines therapeutics with the improvement of oxygen and ventilation support when relevant, capacity building and training activities focusing on effective use of treatment and prevention strategies.

Development of antibiotics and diagnostics are considered **out of scope.** However, use of diagnostics as standard of care addressing differential diagnosis is permissible.

Preclinical studies are considered out of scope of the topic.

However, preparatory activities conducted during the preclinical phase can be considered in scope if they enable the conduct of the clinical study/ies in scope (these activities include but are not limited to protocol writing, development/evaluation of laboratory tests, CMC related activities, etc.).

The purpose of this topic is to fund a varied portfolio of LRTI related projects. In addition, it is highly important to implement solutions as soon as possible, in particularly for health solutions which have shown improved health outcomes in other regions of the world as EU and US. The granting authority will therefore base its funding decision relevant to this topic on the ranking of the proposals taking into account diversity of the respective diseases targeted in the proposals that are graded above the threshold as well as taking into account late-stage proposals, for proposals that are graded above the threshold.

For all Global Collaboration Actions such as this topic, proposals submitted are expected to leverage financial and/or in-kind contribution from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners. Each contribution should be well described and budgeted in each proposal, so that the activities and related costs that are covered by the in-kind or financial contribution(s) are clearly identified.

The applicants are encouraged to consider the latest innovations and advances in the clinical trial design and research methods in order to evaluate promising interventions allowing shorter development timings. Applicants are also encouraged to follow the WHO Guidance for best practices for clinical trials.

Where possible, collaboration and coordination with the AU-EU Health Partnership's Manufacturing and Access to Vaccines, medicines and health technologies (MAV+) hub or similar African initiatives is encouraged. Applicants could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from SSA countries, including involvement of Franco/Lusophone countries, if possible. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

Proposals should clearly describe the desired Target Product Profile. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation and an access strategy that will allow patients in low-resource settings to access the final product.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines and are encouraged to follow guidance provided in the EDCTP Knowledge Hub Research into Policy Toolkit.

Expected impact

The actions funded under this topic should contribute to achieve the reduction of disease burden in SSA through increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investment.

Proposals are expected to include the effective in-kind and/or financial contribution of contributing partners, in order to produce more meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation (EU) 2021/2085[68]). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit a first draft of the endorsement letter to the Programme Office before the deadline for submission of the second-stage applications[69]. For details on the process on becoming a Global Health EDCTP3 contributing partner, please consult the Guide for contributing partners.

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate, i.e. as beneficiaries or affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement. Also, Global Health EDCTP3 contributing partners can be a country, an international organisation or any public or private legal entity, other than the Global Health EDCTP3 members or their constituent or affiliated entities (please consult the Guide for contributing partners.).

[68] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

[69] The Global Health EDCTP3 Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 website or is missing any compulsory elements. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 Governing Board.

Specific conditions to the topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 8.475 million per project to be matched by an equal or greater financial and/or in-kind contribution from other contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 33.878 million. The budget for this call topic may increase, subject to the confirmation of the Novo Nordisk Foundation as a Contributing Partner.
Type of action	Research and Innovation Action (RIA)
Award criteria	In addition to the aspects of award criteria included in General Annex D, the following aspects must be taken also into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant research activities via the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085[70], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results[71] an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and

[70] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17*.

[71] For more information on the Plan for the exploitation and dissemination of results, please consult the General Annexes of Horizon Europe Work Programmes.

	manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). The plan is to be submitted with the second-stage proposal. In addition to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085,[72] participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

[72] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

Global Health EDCTP3

Co-funded by the European Union

HORIZON-JU-GH-EDCTP3-2026-01-HIV-03-two-stage: Global collaboration action towards better prevention, treatment and clinical management of HIV co-infections or co-morbidities in sub-Saharan Africa

Type of action: Research and Innovation Action (RIA)

EU budget: EUR 25 million (to support up to 5 projects).

Background

Despite the shifting global health research funding landscape and resources increasingly being re-focused to other emerging (health) priorities, HIV continues to be a major driver of morbidity and mortality, particularly in sub-Saharan Africa (SSA) that is home to nearly 70% of all people living with HIV worldwide. A growing challenge for this region is the increasing number of people living with HIV and related co-infections and co-morbidities. This includes people living with HIV who are infected with another infectious pathogen (in particular but not limited to tuberculosis, malaria, genital schistosomiasis, hepatitis and human papillomavirus) as well as people living with HIV having a non-communicable disease (NCDs), in particular but not limited to cardiovascular diseases and diabetes. HIV co-infections and co-morbidities are typically associated with polypharmacy which complicates treatment decisions, increases the serious risk of drug-drug interactions and influences the effectiveness or safety of treatments. According to the World Health Organization[73], 73% of all NCD deaths are in Low- and Middle-Income Countries (LMICs) making NCDs a major cause of mortality. There is therefore an urgent need to improve prevention, treatment and clinical management of people living with HIV and related co-infections and co-morbidities by accelerating clinical research for new/improved (combination) products and clinical management practices. Given the importance of patient-centred approaches to healthcare, studies examining how prevention or treatment of non-communicable diseases can be integrated into models of care established for the management and treatment of HIV are essential.

Expected outcomes

Proposals submitted under this topic should aim for delivering results that are directed, tailored towards and contributing to ALL of the following expected outcomes:

1. Improved prevention and/or treatment outcomes for co-infection(s) or co-morbidity/ies to HIV in SSA.
2. Better integration of healthcare services and support programs related to HIV co-infection(s) or co-morbidity/ies for people living with HIV in different healthcare systems in SSA.
3. Improved management of people living with HIV and related co-infection(s) or co-morbidity/ies, particularly safer polypharmacy use.
4. Enhanced and informed public health management decision-making by policy makers and public health authorities with regards to people living with HIV and related co-infection(s) or co-morbidity/ies.

[73] WHO website –- Noncommunicable diseases fact sheet (23 December 2024)

Scope

The proposals submitted under this topic should generate evidence on efficacy, immunogenicity, safety and/or clinical utility for healthcare professionals and clinicians in SSA of novel/improved products that aim to improve prevention and/or treatment outcomes for a co-infection or co-morbidity to HIV.

This includes the prevention of developing HIV co-morbidities or advanced HIV disease (as per WHO definition[74]). Proposals should address effective service integration in different healthcare systems in SSA, including safer polypharmacy use.

The proposals submitted under this topic should address late-stage (phase IIb and thereafter) clinical development.

The target population is people with HIV, including advanced HIV disease associated with co-morbidities and patients on long term HIV treatment (including antiretroviral and HIV control). Except for Tuberculosis (covered in other call for proposals), all infectious diseases and co-morbidities in this target population are within the scope of this topic. The clinical research may also include advanced HIV disease associated with co-morbidities. Existing high-risk co-morbidities and those attributed to the use of medications or other interventions to treat HIV are also in scope.

The research can be conducted in any age group, but it should be inclusive when relevant and ensure the participation of vulnerable research participants, for example but not limited to people living with HIV having impaired organ function. Social and societal dimensions including strategies for social inclusion and stigma mitigation are to be considered. Sex and gender differences and the effects of age should be duly taken into account when relevant. For Phase III studies, applicants are encouraged to ensure adequate statistical power for sex/gender- and age-specific analyses when relevant.

The proposals should address how the generated data will support public health authorities and policy makers to inform updated evidence-based clinical guidelines and design relevant HIV policies.

Cost-effectiveness and implementation research is within the scope of this topic, especially in the context of new innovations such long acting injectables and monoclonal antibodies. For long-acting injectables and monoclonal antibodies in particular, the implementation research should consider cost-effectiveness studies or other activities to make interventions affordable and accessible.

Epidemiological and surveillance studies with new cohorts and development or evaluation of diagnostics are out of scope of this topic. However, the continuation of surveillance of existing cohorts and the use of diagnostics as part of the standard of care when relevant is permissible.

The prevention and treatment of a HIV infection itself or clinical management exclusively focusing on HIV infection is also **out of scope** of this topic. The assessment of HIV parameters developing interventions for co-infections or co-morbidities or in clinical management is in scope.

Preclinical studies are considered out of scope of the topic.

However, preparatory activities conducted during the preclinical phase can be considered in scope if they enable the conduct of the clinical study/ies in scope (these activities include but are not limited to protocol writing, development/evaluation of laboratory tests, CMC related activities, etc.).

For all Global Collaboration Actions such as this topic, proposals submitted are expected to leverage financial and/or in-kind contribution from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners. Each

[74] WHO | Global HIV Programme

contribution should be well described and budgeted in each proposal, so that the activities and related costs that are covered by the in-kind or financial contribution(s) are clearly identified.

Where possible, collaboration and coordination with the AU-EU Health Partnership's Manufacturing and Access to Vaccines, medicines and health technologies (MAV+) hub is encouraged. The proposers could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

When relevant, proposals should clearly describe the desired target product profile. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation and an access strategy that will allow patients in low-resource settings to access the final product.

The applicants are encouraged to consider the latest innovations and advances in the clinical trial design and research methods in order to evaluate promising interventions allowing shorter development timings.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers, healthcare professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines and are encouraged to follow guidance provided in the EDCTP Knowledge Hub Research into Policy Toolkit.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from SSA countries, including involvement of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, such as external conferences, workshops or symposia for an exchange of knowledge, and best practices with external collaborators.

Expected impact

Projects funded under this topic should contribute towards the reduction of the burden of disease in sub-Saharan Africa and thus contribute to achieving SDG 3 'Ensure healthy lives and promote well-being for all at all ages' through increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investment.

Proposals are expected to include the effective in-kind and/or financial contribution of contributing partners, in order to produce more meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation

(EU) 2021/2085[75]). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit a first draft of the endorsement letter to the Programme Office before the deadline for submission of the second-stage applications[76]. For details on the process on becoming a Global Health EDCTP3 contributing partner, please consult the Guide for contributing partners.

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate i.e. as beneficiaries or affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement. Also, Global Health EDCTP3 contributing partners can be a country, an international organisation or any public or private legal entity, other than the Global Health EDCTP3 members or their constituent or affiliated entities, please consult the Guide for contributing partners.

Specific conditions to this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 5 million per project to be matched by an equal or greater financial and/or in-kind contribution from other contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 25 million.
Type of action	Research and Innovation Action (RIA)
Award criteria	In addition to the aspects of award criteria included in General Annex D, the following aspects must be taken also into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant research activities via the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.

[75] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

[76] The Global Health EDCTP3 Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 website or is missing any compulsory elements. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 Governing Board.

Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085[77], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results[78] an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). The plan is to be submitted with the second-stage proposal. In addition to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085[79], participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions.

[77] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17*.

[78] For more information on the Plan for the exploitation and dissemination of results, please consult the General Annexes of Horizon Europe Work Programmes.

[79] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

	3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

HORIZON-JU-GH-EDCTP3-2026-02-CH-01-two-stage: Global collaboration action on climate and health in sub-Saharan Africa

Type of action: Research and Innovation Action (RIA)

EU Budget: EUR 25 million (to support up to 5 projects).

Background

Research shows that 3.6 billion people already live in areas highly susceptible to climate change. Climate change is expected to cause worldwide approximately 250,000 additional deaths per year, from malnutrition, malaria, diarrhoea and heat stress between 2030 and 2050[80].

Despite its low contribution to the drivers of climate change, Africa will bear high consequences of the changing climate, indicated by rising climate-related health emergencies accounting for more than half of public health events recorded in the region over the past two decades[81]: Out of the 2100+ public health events recorded in the African region between 2001 and 2021, 56% were climate-related. The region is witnessing an increase in climate-linked emergencies, with 25% more climate-related events recorded between 2011 and 2021 compared with the previous decade. More particularly, water-borne diseases accounted for 40% of the climate-related health emergencies over the past two decades [82]. Vector-borne diseases, notably yellow fever, accounted for 28% of the climate-related health emergencies, while zoonotic diseases, specifically Congo-Crimean haemorrhagic fever, being the third most prevalent [83]. Where appropriate, a “One Health” approach is recommended to address climate-related public health events. The approach is based on the premise that human, animal and ecosystem health is interconnected and requires a coordinated approach to tackle and resolve the challenges.

In addition, vulnerable populations in Africa, particularly the low-income households, women, children, and rural communities, are disproportionately affected by climate change because they face higher exposure to extreme weather, depend heavily on climate-sensitive agriculture productivity, and have limited resources and institutional capacity to adapt, which deepens poverty, food insecurity, health risks, and displacement.

Changing climate conditions (such as temperature, humidity and precipitation levels) have an impact on the geographical and seasonal distribution of infectious diseases, with weather affecting the timing and intensity of disease outbreaks. This results in particular disease-carrying vectors becoming of relevance for Europe. In addition to climatic factors, regional disease risks are also affected by factors such as land use, vector control, human behaviour, global trade and travel, and public health capacities[84].

Climate change is also increasing Europe’s risk to water-borne diseases by degrading water quality through flooding, heatwaves, and droughts, thereby heightening risks of gastrointestinal infections and other health issues, especially when sanitation and infrastructure are inadequate [85].

With this, the **European Commission’s Strategic Research and Innovation Agenda on Health and Climate Change**[86] – launched in mid-2025 – sets out a comprehensive R&I roadmap with cross-cutting priorities including climate-driven health inequalities, inter-sectoral data systems, climate adaptation in healthcare systems, and the development of transdisciplinary, global knowledge

80 WHO | Climate Change
81 WHO | Africa faces rising climate-linked health emergencies
82 Idem
83 idem
84 Vector-borne diseases | Health effects | European Climate and Health Observatory Climate-ADAPT
85 Water-borne disease | Health effects | European Climate and Health Observatory Climate-ADAPT
86 Strategic research and innovation agenda on health and climate change - Publications Office of the EU

partnerships (HERA, EC DG RTD, SRIA 2025). This prioritisation underscores the alignment between the EC's SRIA and Global Health EDCTP3 objectives, emphasising the need for integrated, equitable, and internationally cooperative research efforts addressing climate-change driven infectious diseases.

Together, these frameworks and epidemiologic trends demonstrate the **urgent need** for Global Health EDCTP3 to fund research on climate-sensitive water- and vector-borne diseases – with a potential dual focus on **sub-Saharan Africa** (SSA), where the burden is high and rising, and **Europe**, where endemic risk is rapidly emerging. In this effort, vulnerable populations in SSA should not be left behind.

Investments in surveillance, climate-adaptive early warning systems, diagnostic and genomic capacity, vector control innovations, One Health approaches, and health system resilience are essential. Aligning with Africa CDC/AU and EC SRIA targets, Global Health EDCTP3 can catalyse cross-continental innovation, strengthen global health security, and mitigate an escalating threat to relevant vulnerable populations.

Expected outcomes

Proposals submitted under this topic should aim to deliver results that are contributing to improved health outcomes related to climate sensitive vector- and water-borne pathogens in the scope of the Global Health EDCTP3 SRIA[87] in SSA.

In addition, proposals are also expected to lead to:

1. Improved health outcomes related to climate sensitive vector- and water-borne pathogens in the scope of the Global Health EDCTP3 SRIA with dual focus on SSA and Europe, and/or
2. Enhanced evidence-based decision-making related to mitigating the impact of climate change on the health of SSA populations based on study data, and/or
3. Increased community and primary health care engagement towards lowering the burden of climate-sensitive vector- and water-borne diseases in the scope of the Global Health EDCTP3 SRIA.

Scope

Proposals under this topic should include:

A/ Minimum one of the following:

1. Conduct a phase IIb or III clinical trial, or post-authorisation effectiveness (phase IV) trial developing a preventive or therapeutic medicine, or vaccine against the pathogens in scope, OR
2. Conduct large-scale implementation research on a validated (corresponding to Technology Readiness Level 8) medical device or novel vector control intervention for pathogens in scope in the context of integrated disease control interventions (which may include surveillance systems, early warning tools, diagnostics, and vector control innovations).

B/ In addition, proposals should address ALL of the following:

1. Where appropriate, integrate the OneHealth aspect in the research, the cross-over between human health with environmental and animal health (guidelines EU for OneHealth incorporation in climate and health). Package interventions could also be considered here.

[87] Global Health EDCTP3 Strategic Research and Innovation Agenda

2. Encompass primary health care systems, community health workers and the community into the study.
3. Include underserved and vulnerable populations such as children under five, pregnant women, elderly people, people with co-morbidities, immunocompromised people, and displaced populations including those living in informal settlements in urban or peri-urban areas as relevant.

C/ In addition, the proposals should address at least two of the following:

1. Include indigenous populations as defined per national/regional context.
2. Study the impact of climate change on supply chains and access to medical countermeasures.
3. Involve local, regional or national health and climate authorities/policymakers, bridging the gap between research and policymaking.
4. Integrate research in national adaptation plans and National Health Emergency Plans.
5. Include adaptations of primary health care systems to climate change, for example infrastructural improvements or the training of the primary care workforce.

Climate-sensitive infectious diseases are defined in scope of this call as diseases whose incidence, prevalence, or intensity is negatively impacted by climate change and includes the vector- and water-borne pathogens in the scope of the Global Health EDCTP3 SRIA.

Proposals are encouraged to integrate climate-epidemiological models integrating humans, animals and ecosystems under different climate scenarios and to indicate how it will contribute to improving the preparedness of health security related to climate sensitive pathogens in (Southern) EU.

Preclinical studies are considered out of scope of the topic.

However, preparatory activities conducted during the preclinical phase can be considered in scope if they enable the conduct of the clinical study/ies in scope (these activities include but are not limited to protocol writing, development/evaluation of laboratory tests, CMC related activities, etc.).

For all Global Collaboration Actions such as this topic, proposals submitted are expected to leverage financial and/or in-kind contributions from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners. Each contribution should be well described and budgeted in each proposal, so that the activities and related costs that are covered by the in-kind or financial contribution(s) are clearly identified.

Applicants are to provide data on the impact of climate change on the chosen disease, and how the proposed study would ameliorate the negative impact.

Applicants will be expected to include a fair representation of health and climate experts and One Health experts in their consortium composition, as relevant, and provide methodologies for translating research findings into public health/climate practice and policy guidelines and are encouraged to follow guidance provided in the EDCTP Knowledge Hub Research into Policy Toolkit. Multidisciplinary approaches with the integration of adjacent sectors are encouraged (i.e. nutrition, IPC/WASH, etc.).

When relevant, proposals should clearly describe the desired target product profile. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation and an access strategy that will allow patients in low-resource settings to access the final product.

The applicants are encouraged to consider the latest innovations and advances in the clinical trial design and research methods in order to evaluate promising interventions allowing shorter development timings. Applicants are also encouraged to follow the WHO Guidance for best practices for clinical trials.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers, health care professionals, policy makers, public health authorities and end-users.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from SSA countries, including involvement of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, and local data collected, the development and adoption of best practices, external conferences joint communication and dissemination activities. Applicants should anticipate budget to cover this collaboration. The details of these joint activities will be defined during the grant agreement preparation phase. Collaboration and coordination with existing adaptive platform trials in Africa and Europe, EDCTP's Networks of Excellence and other EDCTP funded initiatives is encouraged, where relevant.

Expected impact

Projects funded under this topic should contribute towards the reduction of the burden of disease in SSA and thus contribute to achieving SDG 3 'Ensure healthy lives and promote well-being for all at all ages and SDG 13, 'Climate Action' through increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investment.

Proposals are expected to include the effective in-kind and/or financial contribution of contributing partners, in order to produce more meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation (EU) 2021/2085[88]). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit a first draft of the endorsement letter to the Programme Office before the deadline for submission of the second-stage applications[89]. For details on the process on becoming a Global Health EDCTP3 contributing partner, please consult the Guide for contributing partners.

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate i.e. as beneficiaries or affiliated entities in the meaning of Article 8 of the Horizon Europe model grant

[88] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

[89] The Global Health EDCTP3 Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 website or is missing any compulsory elements. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 Governing Board.

agreement. Also, Global Health EDCTP3 contributing partners can be a country, an international organisation or any public or private legal entity, other than the Global Health EDCTP3 members or their constituent or affiliated entities (please consult the Guide for contributing partners).

Specific conditions to this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 5 million per project to be matched by an equal or greater financial and/or in-kind contribution from other contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 25 million.
Type of action	Research and Innovation Action (RIA)
Award criteria	In addition to the aspects of award criteria included in General Annex D, the following aspects must be taken also into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant research activities via the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085[90], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results[91] an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect

[90] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17*.

[91] For more information on the Plan for the exploitation and dissemination of results, please consult the General Annexes of Horizon Europe Work Programmes.

	ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). The plan is to be submitted with the second-stage proposal. In addition to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085[92], participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

[92] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

HORIZON-JU-GH-EDCTP3-2026-03-SERP-01: Training and innovation networks for sustained capacity development related to ethics, regulatory, pharmacovigilance, and related digital regulatory platforms

Type of action: Coordination and Support Action (CSA)

EU budget: EUR 15 million (to support up to 10 projects).

Background

Ethics bodies, regulatory agencies, and pharmacovigilance (PV) systems in sub-Saharan Africa (SSA) continue to face significant challenges that hinder effective provision of healthcare services, safety reporting and timely regulatory approval for clinical trials, and marketing authorisation of products. These challenges are largely attributed to limited resources, limited training provision and access to mentor expertise, governance constraints, disparities in digital infrastructure, and limited regional and international regulatory alignment. In response, initiatives such as the African Vaccines Regulatory Forum (AVAREF), the African Medicines Regulatory Harmonization (AMRH) Programme and most recently the African Medicines Agency (AMA) have been launched to address these gaps. International bodies, including the World Health Organization (WHO), along with partnerships in SSA, have contributed to bridge the gap by offering technical support, training, and resources to strengthen ethics, regulatory and PV capacities. Public-private partnerships have further supported ethics and regulatory capacity strengthening, safety monitoring systems, including the development and integration of digital health technologies to enhance adverse event monitoring and reporting, and to accelerate the regulatory submission and assessment processes through collaborative or joint reviews.

As per the WHO publication of October 2025[93], eight SSA National Regulatory Authorities (NRAs)—Ghana, Nigeria, South Africa, Tanzania, Rwanda, Senegal, and Zimbabwe—are classified by WHO as Maturity Level 3 (ML3), indicating reasonably established and functioning regulatory systems. Nevertheless, major hurdles remain, such as the lack of harmonised regulatory standards and timelines, underfunded research ethics committees (RECs) and NRAs, disparities in institutional and digital capacity and sustainability of the systems set up. These issues hinder the timely and consistent evaluation of research protocols and/or applications for marketing authorisation for diagnostics, medicines, and vaccines across the region.

Despite the increasing participation of SSA countries in the WHO Programme for International Drug Monitoring (WHO PIDM), PV systems in many SSA countries remain underdeveloped and insufficiently integrated into national healthcare systems. This is reflected on both pre- and post-authorisation safety monitoring, where systems are weakened by poor digital infrastructure, limited laboratory capacity for confirmation of suspected events, weak reporting tools for data capture and interpretation, and a shortage of trained personnel. This limits the region's ability to ensure effective PV and safety of medicinal products.

Building on the progress made through previous EDCTP initiatives[94], this call aims to scale and sustain these efforts by establishing training, twinning, and innovation networks, leveraging existing networks where applicable that will bolster workforce capacity in ethics, regulatory, and PV and harmonisation of processes and timelines. Central to this approach is the **development of a robust digital health ecosystem**, which will allow seamless collaboration and enhance the **operational efficiency and responsiveness** of ethics, regulatory, and PV frameworks through the integration of

[93] List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4)
[94] EDCTP1-Project-Portfolio-2003-2015.pdf; EDCTP2-Project-Portfolio

data-driven technologies and digital infrastructure, including artificial intelligence (AI) when considered appropriate, catalysing the approval and implementation of health solutions in SSA.

Expected outcomes

Proposals submitted under this topic should aim to deliver results that are contributing to increased regulatory capacity of (national, regional (supranational) or continental) Regulatory Authorities for the clinical trial oversight, registration and marketing authorisation and/or PV functions to operate at WHO maturity level 3 (ML3) as benchmarked against WHO Global Benchmarking Tool[95] for medical products (therapeutics and vaccines) and/or increased research ethics oversight capacity using the WHO Research Ethics Oversight Benchmarking tool[96] including streamlining and coordinating ethics oversight for multi-centre trials for medical products (therapeutics and vaccines) within countries.

In addition, proposals are expected to lead to at least two of the following:

1. Improved digital infrastructure including emerging digital technologies (i.e. AI and/or big data) in SSA for the assessment of clinical trial protocols by RECs and/or regulatory authorities and/or applications for marketing authorisation by regulatory authorities.
2. Availability and accelerated use of digital technologies and data analytics, for real-time safety data monitoring and reporting, and timely PV data sharing across countries in SSA and globally through PIDM, for pre- and post-authorisation PV processes.
3. Greater harmonisation, coordination and streamlining of research ethics processes within countries to allow for efficient processes for ethics review of multi-centre trials.
4. Greater alignment and cooperation across countries in SSA regarding global standards in ethics, regulatory and PV.
5. Greater preparedness for emergency use authorisation [incl. authorisation of Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI)] through implementation of accelerated and harmonised processes.

Scope

Proposals submitted under this topic should address persistent gaps in ethics, regulatory and/or PV systems evaluating medical products (therapeutics and vaccines) by strengthening existing and/or building new networks:

1. Proposals should address the capability to provide scientific advice, enhancement of knowledge on assessing complex innovative clinical trial applications (included but not limited to platform trials) and/or assessing marketing authorisation files, and/or PV capabilities including AI and big data as appropriate, strengthening capacity for ethics committees and/or regulatory agencies that did not reach ML3 for the corresponding areas as defined in the WHO Global Benchmarking Tool, while benefitting from mentoring/peer support by ML3/ML4 agencies as part of the consortium.
2. Proposals should establish and strengthen training and twinning networks or a regional regulatory authority dedicated to training ethicists and regulators to ensure sustainable capacity for Ethics Committees, and/or Regulatory Authorities and/or PV across countries in SSA in alignment with international standards.

In addition, proposals should address minimum one of the below:

[95] WHO | Global Benchmarking Tools
[96] WHO | Benchmarking tool for ethics oversight of health-related research in humans

1. Building national and/or regional/continental ethics and regulatory capacity to utilise digital technologies, improving the review and approval processes and knowledge of clinical trial applications (including acceleration through parallel ethics and regulatory review), and/or marketing authorisation of medicinal products.
2. Improving integration of PV systems into national health systems by building and utilising digital reporting mechanisms and data sharing across countries in SSA in alignment with international standards:
    a. Implementation of collaborative digital platforms for accelerated use of digital reporting mechanisms to support joint reviews and collaboration in PV, enabling more efficient sharing of data on Adverse Drug Reactions (ADRs) from site to national systems and beyond national (e.g., WHO Programme for International Drug Monitoring (PIDM)) and/or
    b. Improve safety reporting by improving the quality of the adverse event reports as well as enhancing the geographical coverage of the reported data, and/or
    c. Strengthen pre- and post-authorisation PV systems including risk-benefit analysis.
3. Improving regulatory and ethics framework and infrastructure for emergency preparedness:
    - Harmonisation of processes, fostering reliance, implementation and use of digital collaboration platforms to support joint reviews.
        a. Establishing continental and global ethics and regulatory peer support and twinning networks.
        b. Establishing continental and global regulatory innovation networks working on alternative pathways for licensure and on the vision of “ONE WORLD, ONE DOSSIER”.

Proposals should ensure capacity building across countries in SSA, including a leadership development program such as training of trainers for ethics capability building, and knowledge sharing across countries in SSA.

Proposals should address how to increase awareness and development of policy on data protection in the context of storage of data when relevant.

Proposals are encouraged to consider capacity strengthening strategies that align with the One Health Approach[97].

Proposals are encouraged to address relevant ethics, legislative and regulatory gaps most pertinent to the SSA countries for strengthening the (digital) platform and to extend the region covered addressing regional/continental needs.

Proposals are encouraged to ensure that ethics and regulatory capacity strengthening are well aligned and progress in parallel.

Applicants should provide methodologies for translating research findings into public health practice and policy guidelines and are encouraged to follow guidance provided in the EDCTP Knowledge Hub Research into Policy Toolkit.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers or clinical Investigators, health care professionals, policy makers, public health authorities and end-users.

Out of scope: Capacity building related to Manufacturing activities for pharmaceutical/vaccines products including but not limited to batch release, support for local manufacturing of active pharmaceutical ingredients (APIs) and Technology Transfer, diagnostic production, financing, strategic

[97] WHO | Definition of One Health

and policy Support Mechanisms for manufacturing are **out of the scope** of this topic. However, the scope includes strengthening of NRAs capacity to carry out manufacturers inspections enabling registration and marketing authorization of medical products.

Financial contributions from third parties (e.g., foundations) interested in this scheme are encouraged to contribute to increase the budget, diversity and impact. The purpose of this topic is to fund different regions and varied portfolio of ethics, regulatory and PV projects. The granting authority will therefore base its funding decision relevant to this topic on the ranking of the proposals considering diversity of the geography and topics (Ethics/Regulatory/PV) in the proposals that are graded above the threshold.

Activities such as willingness to enter into technology transfer agreements with their counterparts - including the provision of patents, technical knowledge and know-how, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market to be done in collaboration and coordination, when possible, with the AU-EU Health Partnership's Manufacturing and Access to Vaccines, medicines and health technologies (MAV+) hub or similar African initiatives are encouraged to be done outside the scope of this topic.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from SSA countries, including active participation of Franco/Lusophone institutions. Collaboration with other international research groups with relevant experience is very much encouraged.

Proposals should include the development or implementation of common indicators (e.g., WHO benchmarking data tools) in assessing the status and functioning of Ethics Committees or Regulatory Authorities towards alignment with global standards.

Expected impact

Through strategic capacity building, digital transformation, and cooperation in SSA, the actions funded under this topic should contribute to the establishment of a resilient and future-ready ethics, regulatory and PV environment.

Applicant consortium

If requested by the applicant consortia, the EDCTP Association may offer technical support for the preparation of their proposal, in particular because of the lump sum nature of the Grant Agreement. The applicant consortia may also decide to include the EDCTP Association as coordinator. In that case, the applicant consortia should contact the EDCTP Association to obtain the estimated amount of the Association's contribution as well as any other relevant information. The EDCTP Association will timely provide the necessary information to all potential applicants.

Specific conditions to this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of around EUR 1.5 million per grant would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 15 million.

	The budget for this call topic may increase, subject to the confirmation of CEPI as a Contributing Partner.
Type of action	Coordination and Support Action (CSA)
Admissibility and eligibility conditions	The applicant consortia may opt for including in their proposal the EDCTP Association as coordinator. In such a case, the eligible costs of the EDCTP Association in the actions funded under this topic will not be reimbursed by the JU and may be used as a basis for in-kind contributions to operational activities (IKOP). The in-kind contribution of the EDCTP Association will cover the coordination activities of the project. In case applicant consortia decides to include the Association as coordinator, they should contact the EDCTP Association in order to inform the Association on their decision and obtain the estimated amount of the Association's contribution as well as any other relevant information. The EDCTP Association will timely provide the information to all potential applicants. The EDCTP Association must not be counted as one of the three independent legal entities necessary to ensure the eligibility of the consortium composition, as requested in the Call conditions, "Specific conditions to Global Health EDCTP3 JU - B. Consortium composition".
Legal and financial set-up of the Grant Agreement – Costs for providing financial support to third parties allowed	Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. The maximum amount to be granted to each third party is EUR 60,000. The relevant provisions of the Model Grant Agreement will apply.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu
Other requirements	For all projects under this topic, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

Global Health EDCTP3

Co-funded by the European Union

HORIZON-JU-GH-EDCTP3-2026-03-DIGIT-02: Enhancing integrated research and healthcare in sub-Saharan Africa through digital innovation and Artificial Intelligence

Type of action: Coordination and Support Action (CSA)

EU Budget: EUR 18 million (to support up to 8 projects)

Background

Digital health has the potential to reshape and enable the implementation of integrated research and healthcare delivery across sub-Saharan Africa (SSA), especially in communities that are underserved or hard to reach. With tools such as mobile health platforms, electronic health records, and the use of artificial intelligence (AI), health services can become more efficient and accessible, responding to the needs of strengthening the research and development settings in SSA. Despite the ongoing rapid advances, SSA countries are still lagging behind, and there is an increasing gap with the developed world where digital innovation and machine learning is expected to deliver significant changes to healthcare. Digital tools currently in use are fragmented, incompatible with each other, and limited in their reach. In addition, the use of AI is creating more opportunities, but there is a need to ensure future technologies are based on models that include data from SSA countries.

Recent strategies, including the WHO's Global Strategy on Digital Health (2020–2025), the African Union's Digital Health Framework, and the Africa CDC's Digital Transformation Strategy, call for urgent action. These frameworks emphasise the need to invest in people-focused, sustainable digital solutions that are locally informed and globally aligned.

This Coordination and Support Action (CSA) focuses on addressing these disparities. It aims to bring together national governments, regional institutions, researchers, healthcare providers, and private sector partners to better coordinate efforts, share knowledge, and build the infrastructure needed to support inclusive, scalable digital health systems.

By aligning with these strategic directions, this CSA promotes a shared vision: one where digital innovation strengthens local health systems rather than working in silos. The goal is not to create new technologies, but to make better use of what already exists by improving coordination, strengthening human capacity, and supporting evidence-based policies and investments that can unlock the true potential of digital health across the region.

Expected outcomes

The proposals submitted under this topic should aim to deliver results contributing to at least two of the below:

1. Scaled-up implementation of validated digital innovations at national or sub-regional level.
2. Improved data interoperability and data harmonisation of electronic health records between different digital health systems according to international standards.
3. Integrated comprehensive roadmap for the sustainable and scalable integration of digital health tools into clinical trials and public health systems in SSA, in line with international standards and local ethical standards, and in the context of sharing of best practices.
4. Increased retention of skilled experts in digital health, epidemiology, bioinformatics, AI in SSA.

Scope

The proposals submitted under this topic should address the following points:

1. Strengthen health systems, capacity and partnership to enhance the development and use of existing and new digital health records and tools, leveraging machine learning and AI, aiming to prevent, detect or treat infectious diseases in the scope of Global Health EDCTP3 in SSA, enabling health care workers, government, and policy makers to make informed clinical decisions or implement well-informed epidemic preparedness measures. Proposals should favour low-risk digital/AI approaches.
2. Strengthen national and regional efforts across SSA with concrete demonstration of scale up of validated digital technologies for implementation at national or sub-regional level, and to align digital health strategies with applicable international best practices.
3. Improved coordination between stakeholders promoting collaborative platforms and partnerships sharing data and knowledge between regions/countries in SSA and ideally with global partners.

Proposals should include sharing of knowledge between countries with advanced systems and those that have lower capacity in terms of digital tools and skills. Proposals should also use applicable international standards for data use and governance including data privacy and data ownership.

Proposals should consider addressing the societal impact and acceptability of the approach by the populations concerned and should demonstrate compliance with applicable ethics requirements for the use of digital technologies in involved SSA countries.

Proposals should address the audit of the bias of the AI system and address the sustainability of the project outcome beyond the project duration.

Proposals are encouraged to consider expansion of robust, user-friendly digital platforms to grow with the regional needs to reach a broad population of patients, health care workers, government, and policy makers.

Proposals should also ensure equity across involved countries in SSA and in relation to other countries where similar technologies are being developed and/or implemented.

Proposals should look into supporting national and regional (supranational) efforts to align digital health strategies with international best practices. Proposals are encouraged to include the sharing of knowledge between countries with advanced systems and less experienced countries having basic digital infrastructure.

Proposals are encouraged to include hands-on practical capacity-building activities preparing institutions and professionals to lead digital transformation efforts as well as digital health policy dialogues.

The applicants are also encouraged to align with the WHO AFRO and Africa CDC strategies for digital health.

Proposals should include a clear plan for how digital tools will be made accessible and affordable to users. Outcomes should be shared publicly, when possible, especially if they serve the public good or have broad regional relevance.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers or clinical Investigators, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines and are encouraged to follow guidance provided in the EDCTP Knowledge Hub Research into Policy Toolkit.

Where possible, collaboration and coordination with the AU-EU Health Partnership's Manufacturing and Access to Vaccines, medicines and health technologies (MAV+) hub or similar African initiatives is encouraged. The applicants could show, for example, willingness to enter into technology transfer agreements with their counterparts - including the provision of patents, technical knowledge and know-how, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from SSA countries, including active participation of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to institutions/organisations in countries with high disease burden but with relatively lower research capacities.

Expected impact

The actions funded under this topic should contribute to strengthening clinical human capital base in R&I, enhancing talent retention, knowledge sharing of best practices within the research and innovation landscape, accelerate integration of digital tools into health systems, expand and scale up validated innovations with tangible implementation at national and/or sub-regional levels.

Applicant consortium

If requested by the applicant consortia, the EDCTP Association may offer technical support for the preparation of their proposal, in particular because of the lump sum nature of the Grant Agreement. The applicant consortia may also decide to include the EDCTP Association as coordinator. In that case, the applicant consortia should contact the EDCTP Association to obtain the estimated amount of the Association's contribution as well as any other relevant information. The EDCTP Association will timely provide the necessary information to all potential applicants.

Specific conditions to this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of around EUR 2.25 million per project would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 18 million. The budget for this call topic may increase, subject to the confirmation of CEPI as a Contributing Partner.
Type of action	Coordination and Support Action (CSA)
Admissibility and eligibility conditions	The applicant consortia may opt for including in their proposal the EDCTP Association as coordinator. In that case, the eligible costs of the EDCTP Association in the actions funded under this topic may not be reimbursed by the JU and may be used as a basis for in-kind contributions to operational

	activities (IKOP). The in-kind contribution of the EDCTP Association will cover the coordination activities of the project. In case applicant consortia decides to include the Association as coordinator, they should contact the EDCTP Association in order to inform the Association on their decision and obtain the estimated amount of the Association's contribution as well as any other relevant information. The EDCTP Association will timely provide the information to all potential applicants. The EDCTP Association must not be counted as one of the three independent legal entities necessary to ensure the eligibility of the consortium composition, as requested in the Call conditions, "Specific conditions to Global Health EDCTP3 JU - B. Consortium composition".
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

4.1.4 Other actions not subject to call for proposals

4.1.4.1 Grant to identified beneficiary

HORIZON-JU-GH-EDCTP3-2026-KHUB-01-IBA: Expansion and consolidation of the EDCTP Knowledge Hub

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) and Article 24(3) (a) of the Horizon Europe Regulation - Coordination and Support Action

EU budget: EUR one (1) million

UNOPS, implementing structure of The Global Health Network (TGHN) is an identified partner to expand and consolidate the EDCTP Knowledge Hub. Building on over a decade of impactful collaboration with EDCTP programmes, TGHN provides a robust digital platform and a vast globally connected community that uniquely delivers capacity building, drives active knowledge sharing, and implementation of health research system strengthening across sub-Saharan Africa (SSA).

Through expanding the EDCTP Knowledge Hub already hosted on TGHN and extending the successfully developed connecting and convening approaches across all existing and future EDCTP regional Networks of Excellence, outbreak networks and other programmes addressing epidemic preparedness, extending and galvanising these specific activities could powerfully advance the Global Health EDCTP3 theory of change. TGHN’s proven tools, guidance, and community-based engagement approaches leave teams better able to plan, conduct research, and have their findings translated into policy and practice.

TGHN offers a strategic and operationally aligned approach to advancing the objectives outlined in the Global Health EDCTP3 programme logic. Central to Global Health EDCTP3's mission is the enhancement of research capacity, equitable access, and the translation of research into health improvements across SSA. TGHN's established digital platform and extensive global research community of over 1 million active members are uniquely positioned to support these goals.

Over the past decade, TGHN has collaborated with EDCTP programmes, notably through the development and expansion of the EDCTP Knowledge Hub**.** This collaboration has facilitated the development of open access toolkits, dissemination of research tools, training materials, activities such as webinars and workshops and best practices, fostering a culture of knowledge sharing and capacity building among African research institutions and globally. The platform's ability to connect diverse stakeholders has proven instrumental in promoting collaborative research efforts and in addressing regional health challenges effectively.

It is the only open, free and cross-cutting facility that supports knowledge provision for clinical research teams that works across all disease areas, all forms of research and all geographies. Therefore, TGHN has long-term experience of developing, hosting and maintaining the EDCTP Knowledge Hub, including managing its use and facilitating the re-use of resources and tools developed by EDCTP-funded projects over the years.

The return on investment in this work is likely to be strong because these approaches have been proven to deliver standardisation, raised quality, shorter research processes and steps and produce stronger teams.

Expected outcome

This topic aims to deliver results that contribute to the ability to monitor and demonstrate the impact of the Global Health EDCTP3 programme through supporting priority areas as identified in the programme logic, and to provide a direct and measurable way to implement the **WHO Global action plan for clinical trial ecosystem strengthening (**GAP-CTS)[98].

It is envisaged that in particular these resources will support Actions 2, 3 and 5 of GAP-CTS on patient involvement/community engagement; addressing under-represented populations and enabling access to fit for purpose clinical research training resources respectively.

Scope

Expanding the EDCTP Knowledge Hub already hosted on TGHN and extending the successfully developed connecting and convening approaches across all existing and future EDCTP regional Networks of Excellence, outbreak networks and other programmes addressing epidemic preparedness, could powerfully advance the Global Health EDCTP3 theory of change. TGHN's proven tools, guidance, and community-based engagement approaches leave teams better able to plan, conduct research, and have their findings translated into policy and practice.

The proposed scope of work is to support five priority areas identified in Global Health EDCTP3's programme logic where adding these interventions could help Global Health EDCTP3 achieve them with an in-built tracking mechanism. The work will specifically and measurably deliver on following 5 of the 9 component steps within the GAP-CTS:

1. Driving equity, access and inclusion across Global Health EDCTP3-funded projects (Gap 3 of the GAP-CTS – removing barriers)
2. Enabling research centres to act as their own sponsors (Gap 6 of the GAP-CTS – removing regulatory hurdles)
3. Supporting community engagement in research (Gap 2 of the GAP-CTS – CEI)
4. Training and implementation support for WHO trial guidelines and ICH GCP R3; (Gap 5 of the GAP-CTS – training)
5. Facilitating knowledge mobilisation and cross-programme connectivity (Gap 9 of the GAP-CTS – collaboration and networking).

Beyond Global Health EDCTP3 objectives, the proposed work should provide a direct and measurable way for Global Health EDCTP3 to implement the GAP-CTS, generating a strong return on investment by enabling immediate, ongoing and embedded delivery of this action plan.

Expected impact

The action funded under this topic should contribute to:

1. Improved equity, access and inclusion across Global Health EDCTP3-funded projects
2. Enabled clinical research centres to act as their own sponsors
3. Improved supporting for community engagement in research
4. Improved training and implementation of WHO Trial guidelines and ICH GCP R3

[98] WHO | Global Action Plan for Clinical Trial ecosystem Strengthening

5. Facilitated knowledge mobilisation and cross-programme connectivity.

Legal entity

United Nations Office for Project Services (UNOPS)

Specific conditions	
Indicative timetable	Call opening: January 2026 Submission deadline proposal: March 2026
Indicative budget	The total indicative JU budget for the topic is EUR 1 million from the 2026 budget.
Type of action	Coordination and Support Action (CSA)
Admissibility and eligibility conditions	Sole beneficiary: United Nations Office for Project Services (UNOPS)' Due to its unique expertise, funding is exceptionally provided to this international organisation.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu).

4.1.4.2 External expertise, service level agreements and other actions

This action will support the use of appointed independent experts for the monitoring and evaluation of running actions (grant agreement, grant decision, public procurement actions, financial instruments) funded under Horizon Europe and include ethics checks, where appropriate, as well as compliance checks regarding the Gender Equality Plan eligibility criterion. It will also support Service Level Agreements and other actions related to the operational activities of the JU.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative timetable: 2026

Indicative budget: The total indicative JU budget is EUR 1 million (tbc) from the 2026 budget.

4.1.4.3 Mobilisation of research funds in case of Public Health Emergencies

Form of Funding: Grants not subject to calls for proposals according to Article 198(b) for the Financial Regulation or grants subject to a call for proposal

Type of action: Research and Innovation Action (RIA) or Coordination and Support Action (CSA)

Expected outcome: Proposals should set out a credible pathway to contributing to one or several expected impacts of this work programme.

Project results are expected to contribute to the following expected outcome:

Allow the European Union and sub-Saharan African (SSA) countries to respond to Public Health Emergencies.

Work in this area should allow a faster research response to outbreaks of epidemic or pandemic infectious diseases. This will allow the EU and SSA member countries of the EDCTP Association to respond to public health emergencies.

In case of a public health emergency [99] (such as a public health emergency of international concern (PHEIC) according to the World Health Organization; a public health emergency under Regulation (EU) 2022/2371 [100]; or a public health emergency under applicable national frameworks and regulations), funding will be mobilised for:

- In line with Article 198 (b) of the EU Financial Regulation[101], awarding grants without a call for proposals in exceptional and duly justified emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be widely communicated, including on the Global Health EDCTP3 website and to the Horizon Europe National Contact Points. The invitation to apply for funding will be open to all eligible entities or be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances.

and/or

- The award of additional funding for ongoing grant agreements funded through EU Framework Programmes for Research and Innovation to cover additional activities specifically linked to the public health emergency, in exceptional and duly substantiated emergencies. Providing such additional funding to ongoing EU Framework Programmes for Research and Innovation grants that can support pertinent short- and mid-term research efforts to confront the public health emergency will save valuable time and allow addressing the situation with the appropriate urgency. Restricted calls for expression of interest or proposals will develop such additional activities or add additional partners to existing EU Framework Programmes for Research and Innovation actions.

It is expected that quality-controlled data are shared in accordance with the FAIR[102] principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational

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99 Should there be no Public Health Emergency in 2026, the indicative budget may be reallocated.

100 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Text with EEA relevance) OJ L 314 6.12.2022, p. 26. (see https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371&qid=1673372768554)

101 Article 198 (b) of the Financial Regulation 2024/2509 on the financial rules applicable to the general budget of the Union (recast) 'Grants may be awarded without a call for proposals only in the following cases: […] (b) in other exceptional and duly substantiated emergencies'.

102 See the Horizon Europe programme guide available on the Funding & Tenders portal at https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

capacity and exclusion, and procedure are provided in the introduction to this work programme and in parts A to G of the General Annexes to the Horizon Europe work programmes 2026.

The beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency, and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

Specific conditions	
Indicative timetable	It will depend on the Public Health Emergency
Indicative budget	The total indicative JU budget for this topic is EUR 1 million. This amount may be increased through contributions from the EDCTP Association or contributing partners, or by transferring funding from other topics, depending on the type and magnitude of public health emergency, and need for launching actions. Based on Article 110 of the Regulation 2021/2085[103], entities established in other states may be eligible for funding from Global Health EDCTP3 in the event of a call addressing a public health emergency.
Type of action	Research and Innovation Action (RIA) or Coordination and Support Action (CSA)
Procedure	The following derogation to the evaluation procedure described in General Annexes F applies to open invitations to submit applications: In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds. The granting authority may therefore fund in priority proposals that are ranked lower than others, if they target another aspect of the public health emergency that is not tackled yet among the higher ranked proposals.
Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	The action may also include justified derogations from the standard limits to financial support to third parties. It may not be more than EUR 60,000, unless the objective of the action would otherwise be impossible or overly difficult. Where applicable, the relevant grant agreement options will be applied.

[103] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085[104], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results[105] an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). The plan is not required for applications at the first stage of two-stage procedures. In addition to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085[106], participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to

[104] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, *p. 17*.

[105] For more information on the Plan for the exploitation and dissemination of results, please consult the General Annexes of Horizon Europe Work Programmes.

[106] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

	their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.

4.2 In-kind contributions to additional activities plan 2026

4.2 In-kind contributions to additional activities (IKAA) plan

Additional Activities can be accounted for as Private Members' In-Kind Contribution for Additional Activities, when they contribute to the objectives of the Global Health EDCTP3 and are directly linked to its activities, including non-eligible costs of indirect actions funded by the JU, where this is provided for in the present annual additional activities' plan.

IKAA to be initiated in year 2026 (EUR)						
by Specific objective						
Country	**Advance development and use of new or improved technologies**	**Facilitate better alignment of countries around a common Strategic Research and Innovation Agenda**	**Promote networking, building partnerships and strategic alliances**	**Strengthen capacity for epidemics preparedness**	**Strengthen research and innovation capacity**	**Total**
Belgium	-	-	-	-	2.000.000,00	2.000.000,00
France	14.100.000,00	-	200.000,00	516.383,00	2.145.400,00	16.961.783,00
Mozambique	-	-	-	100.000,00	800.000,00	900.000,00
Norway	1.021.450,40	-	-	-	425.604,30	1.447.054,70
Portugal	-	-	-	-	746.000,00	746.000,00
Uganda	13.983.894,60	-	-	-	-	13.983.894,60
United Kingdom	13.200.000,00	-	-	-	-	13.200.000,00
Rwanda	2.000.000,00	-	80.000,00	900.000,00	300.000,00	3.280.000,00
Nigeria	68.000,00	255.704,00	-	-	284.321,00	608.025,00
Namibia	-	-	-	25.000,00	-	25.000,00
Total	**44.373.345,00**	**255.704,00**	**280.000,00**	**1.541.383,00**	**6.701.325,30**	**53.151.757,30**